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This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1988 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 40-23, as amended, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations.

In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is especially grateful to our former Commander, BG THOMAS M. GEER, MC, and BG THOMAS E. BOWEN, MC, Commanding General of Fitzsimons Army Medical Center, the professional and administrative staff, and to the Commanding Officers and staff of other supporting activities for the cooperation and assistance provided this Department of Clinical Investigation in our efforts to accomplish our mission. Finally, I would like to recognize the outstanding work, dedication, and wholehearted corroboration of my entire staff. I would especially like to thank my Research Protocol Specialist, Ms. Marcia Bilak and Ms. Chris Montoya, Secretary, without whose assistance and support this report would not have been possible.

John K. Podgore

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UNIT SUMMARY

Clinical Investigation Program, FAMC

Clinical Investigation efforts by FAMC personnel in FY 88 culminated in the publication of 110 articles and 41 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1988, there were 238 research protocols on the DCI register. Of these, 183 projects were ongoing, 30 projects completed, 17 projects terminated, and for this FY there were 63 new registrations.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medicine. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.
Authorized

<u>Description</u>	Grade	MOS	Br	Auth	Req	Act	Name	Rank
C, Dept Clin Inv	Ø6	6ØP9B	MC	1	1	1	PODGORE	COL
C, Micro Svc	Ø5	68AØØ	MSC	1	1	1	Andron	LTC
C, Psychophys & Biostat Svc	Ø4	68TØØ	MSC	Ø	1	1	Sherman	MAJ
C, Biochem Svc	Ø4	68C9C	MSC	1	1	1	White	MAJ
C, Immunol Svc	Ø4	68EØØ	MSC	1	1	1	Stewart	MAJ
C, Cell Phys Svc	Ø3	68JØØ	MSC	1	1	1	Ferris	CPT
C, Animal Res Svc	Ø4	64C9B	VC	1	1	1	Trahan	MAJ
NCOIC-Med Lab	E7	92B4R		1	1	1	Engle	SFC
Sr Med Lab Sp	E6	92B3R		1	1	1	Fernandez	SSG
Operating Rm Sp	E5	91D2R		1	1	1	Haynes	SGT
Bio Sci Asst	E6	Ø1H3R		1	1	1	Chadwick	SSG
Bio Sci Asst	E6	Ø1H3R		1	1	1	Bradley	SSG
Bio Sci Asst	E5	Ø1H3R		1	1	1	Sanders	SGT
Vet Sp	E6	91T3R		1	2	1	Barrett	SSG
Vet Sp	E5	91T2R		1	1	1	Lamb	SGT
Bio Sci Asst	E4	Ø1H1R		1	1	1	Cruz-Saez	SP4
Bio Sci Asst	E4	Ø1H1R		1	1	1	Williams	SP4
Bio Sci Asst	E4	Ø1H1R		1	1	1	Mendez	SP4
Bio Sci Asst	E4	Ø1H1R		1	1	1	Galvin	SP4
Supv Res Chem	13	132Ø	GS	1	1	1	O'Barr	
Microbiologist	11	Ø4Ø3	GS	3	3	3	Lima Paine Hoyt	

<u>Description</u>	Grade	MOS	Br	Auth	Req	Act	Name	Rank
Microbiologist	09	0403	GS	3	6	3	Morse Tessier Muehlbauer	
Med Technologist	11	0644	GS	0	1	1	Rush	
Med Technologist	09	0644	GS	0	6	5	Ramirez (Term) Chadwick (Term) Pinney (Term) Sachanandani (Term)	
Med Technician	07	0645	GS	1	1	1	Nelson	
*Research Chem	11	1320	GS	*4	*3	*3	Noble Williams Stewart	
Bio Lab Tech (Animal)	09	0404	GS	1	1	1	Mercill	
Animal Caretaker (Foreman)	04	5048	WS	1	1	1	Jones	
Research Prot Sp	09	0301	GS	1	1	1	Bilak	
Animal Caretaker	05	5408	WG	1	3	2	Chase Hitchcock	
Secretary	06	0318	GS	1	1	1	Montoya	

* - The four GS11 chemist requirements are as follows:

One authorization changed to a GS644 Medical Technologist (open)

Two authorizations filled with GS11 Chemists

One overhire on board GS11 Chemist (required but not authorized)

Animal Resources Service - FY 88

New office furnishings were received and installed during FY 88, providing a much more professional work atmosphere. An "Investigator Guide" was completed during the year, in sufficient number to issue to each member of the Laboratory Animal Care and Use Committee and to each prospective investigator. This guide is intended to assist the investigator in the preparation of animal use protocols, and to use laboratory animals in ways judged to be both professionally and humanely appropriate. It is intended to assist committee members in making determinations relative to protocol applications, and to meet, at least in part, the requirements of Public Law 99-198 to provide training for scientists, animal technicians and other personnel involved with animal care and treatment.

Full AAALAC accreditation was restored on 10 March 1988. Fiberglass-reinforced plastic ceiling panels were installed in the dropped-ceiling areas of the animal housing facility, replacing the unacceptable acoustical tiles. Emergency eye washes were fitted to three sink faucets in the service. A safety chain was installed around the cage washer pit to prevent personnel injuries. A new floor scrubber was procured and has been invaluable in the prevention of soil buildup on the roughened floor surfaces in the animal facility. A pushbutton security lock system was installed in the animal facility and in surgery.

Due to the AALAS annual meeting being held in Denver in November 1987, all members of Animal Resources Service and the Laboratory Animal Care and Use Committee were able to attend. Mr. Jones, Animal Caretaker Foreman, and secretary of the Mile High Branch of AALAS, was awarded Branch Member of the Year in May 1988. MAJ Creighton J. Trahan successfully completed written and oral examinations and has been installed as a Diplomate of the American College of Veterinary Preventive Medicine.

Biochemistry Service - FY 88

1988 was a year of upgrade and transition for the biochemistry service. Many physical improvements were made to building 600 to include a new roof, improved wiring and plumbing, new walls, floors, ceilings and a fresh coat of paint inside and out! Everyone made it through the mini-renovation in good spirits and we all enjoy working in a more pleasant, safer environment.

In addition to the renovation to the physical layout we brought on board several new instrument systems. The Perkin-Elmer 5100 PC was put in service to perform trace metal analysis. It is a dedicated Zeeman system using heated graphite atomization (HGA). We are gearing up for blood lead and serum aluminum. Copper, cadmium and zinc will follow. In March, we brought the Packard Cobra gamma counter online. It is now our work horse for glucagon, B₂ microglobulin, cortisol and other I¹²⁵ procedures. We have also acquired the HP Vectra RS/20, a 386 computer with a color plotter and a laser-jet printer which allows us to generate publication quality text and graphics.

We are very excited about our collaboration with the University of Colorado Health Science Center (UCHSC) in support of the Army physicians in the Pediatric Fellowship at UCHSC. The collaboration includes assays such as physiological amino acids, carbohydrates, and nucleic acids. We continue to support a number of basic medical research protocols involving B₂ microglobulin, Hemoglobin A_{1c}, and red cell metabolism. We are beginning a blood lead/zinc protoporphyrin comparison study with both FAMC and OTSG input.

Cell Physiology Service - FY 88

Of major importance has been the successful use of athymic mice from the CPS colony as the support system for a human skin model. This model which is applicable for many human skin research projects is currently being used to investigate the biology of

cutaneous lupus. The study is being carried out in collaboration with the CPS; the Dermatology Service, FAMC; and the Dermatology Department, University of Colorado Health Sciences Center. CPS has also supported the cell biology aspects of research being conducted in growth hormone treatment, hypoxia of newborn intestine, melanoma estrogen receptor analysis, erythroid burst forming growth, herpes simplex virus assay evaluation, and radiolabelled TSH as a possible thyroid cancer diagnostic aid. These studies have emanated from the areas of pediatrics, dermatology, pathology, and endocrinology. To provide support of research at the ultrastructural level of cell biology, the CPS has added to its investigative resources both a new scanning electron microscope and a new transmission electron microscope.

Immunology Service - FY 88

The Immunology Service has had some moderate personnel changes over the past year. Two GS-9 medical technologists, Rosella Schaff and Cynthia Harrison, departed and one GS-9 medical technologist, Anita Gulati, came on board as a replacement for Miss Schaff as part of the Natural History and AZT Study support team. The overhire position once occupied by Mrs. Harrison will probably not be filled due to current budgetary considerations. To date over 1000 individuals, approximately evenly divided between military and civilian, have been evaluated and acquired within the database in support of the Natural History and AZT protocols. Flow cytometric procedures continue to include almost exclusively two-color cell surface analysis, but new procedures for DNA analysis of paraffin embedded tumors, anti-nuclear antibody (ANA) analysis by pattern recognition, and neutrophil activation analysis by flow cytometric measurements are increasing. The Immunology Service was again tasked by Department of the Army with hosting a week long Flow Cytometry Quality Assurance Workshop which this year was expanded to include Air Force and R&D personnel. There are two currently active research protocols, one was completed, two are about to commence operations, and an additional three are undergoing feasibility studies and literature review. New equipment acquired this year include two 80386-based microcomputers, an automatic dispenser/dilutor, a microelectrophoresis system, and a robotics controlled automated ELISA system (placed in Biochemistry). Programmed for procurement FY89 include an automated densitometry and image analysis workstation as well as a radioisotope imaging scanner.

Microbiology Service - FY 88

The successful performance of the mycobacteriology section on all College of American Pathologists (CAP) proficiency surveys was an important part of the successful accreditation of the Fitzsimons AMC pathology laboratory. The mycobacteriology section also supported two research studies: one done in collaboration with the University of Colorado Health Sciences Center involving evaluation of a gene probe method for identification of mycobacteria in primary isolates; another done in collaboration with Colorado State University investigating the use of a panel of over 30 antigens in the rapid diagnosis of *M. avium* in AIDS patients.

Microbiology service support of the AIDS natural history and AZT treatment studies includes viral culture, antibody, antigen, helper-cell, and other state-of-the-art tests for FAMC AIDS patients. Patient entry in this 200 patient treatment study should be complete by Feb 89. This study could be a pivotal study for the early treatment of AIDS with AZT.

Over 500 sera from US Army Reservists were tested for Lyme disease antibodies in collaboration with Fort Leonard Wood personnel. Both ELISA and FIAX tests showed some positives. The ELISA seemed to be much less specific than FIAX. Without an accurate antigen detection or other confirmatory methods, these serologies cannot be considered definitive indicators of presence or absence of Lyme infection.

Psychophysiology & Biostatistics Service - FY 88

The service's missions are to (1) provide a modern Psychophysiology/Pain Evaluation Laboratory for clinical and research evaluations as well as psychophysiological treatments, (2) coordinate, provide opportunities for, and encourage the research related efforts of Orthopedic staff and residents, and (3) provide support to all MEDCEN staff and students in design and analysis of studies as well as psychophysiological techniques. During the service's first full year of operations, all major equipment items required for a state of the art Psychophysiology/Pain Evaluation Laboratory have been procured and put into operation and are being operated by grant funded personnel. All first and third year Orthopedic residents are participating in one or two month research rotations during which they are relieved of all regular clinical duties. Seminars on research design and statistical analysis have been presented to four services outside of Orthopedics and Clinical Investigation and numerous investigators have been helped to design and analyze studies. Research breakthroughs have been made in (1) relating muscle tension patterns recorded continuously in the normal environment and onset of low back pain and (2) induction of acute episodes of phantom pain by discrete spasms in the residual limbs of amputees.

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

		<u>FY 87</u>	<u>FY 88</u>
<u>OMA</u>	Civilian Personnel	653,076.36	668,953.
	Contracts	39,964.93	41,514.
	Supplies	297,881.20	218,000.
	Ceep Equipment	17,215.14	28,599
	Travel	9.076.18	6,552
<u>OPA</u>	MEDCASE	241,152.77	282,809.40
<u>GRANTS</u>	VA (Psychophysiology & Biostatics Service)		
	MPDC (AZT treatment study)		\$116,000

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PUBLICATIONS

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Fitzpatrick JE: Panniculitis. Presented: Combined Skin Pathology Meeting, Colorado Springs, CO, October 1987.

Fitzpatrick JE, Brooke D, and Golitz LE: Papillary Mesenchymal Bodies: A Histologic Finding Useful in Differentiating Trichoepitheliomas from Basal Cell Carcinomas. Presented: American Society of Dermatopathology Annual Meeting, San Antonio, TX, December 1987. (C)

Melette JR: Flap Combination for Large Facial Defects. Presented: American Academy of Dermatology Annual Meeting, San Antonio, TX, December 1987.

Melette JR: Helpful Hints in Dermatologic Surgery. Presented: 11th Annual Tri-Services Dermatology Seminar, San Antonio, TX, May 1988.

Mellette JR: Practical Skin Surgery. Presented: Colorado Dermatology Society, Denver, CO, May 1988.

Melette JR: Benign and Malignant Tumors of the Skin. Presented: 35th Annual Family Practice Review, Denver, CO, September 1988.

Endocrinology Service

Georgitis W, Swanson E, and Noble S: Sustained Prolactin Derangements Fail to Alter Male Rat Gonadal Axis. Presented: The Endocrine Society - 70th Meeting, New Orleans, LA, June 1988. (C)

Georgitis W, Bornemann M: TRH Testing: An Inadequate Confirmatory Test for Subclinical Hypothyroidism. Presented: The Endocrine Society - 70th Meeting, New Orleans, LA, June 1988.

McDermott MT, Perloff JJ, and Kidd GS: Reduced Bone Mass in Mild Asymptomatic Primary Hyperparathyroidism. Presented: American Society for Bone and Mineral Research - 10th Annual Scientific Meeting, New Orleans, LA, June 1988. (C)

McDermott MT, Fortenbery EJ, and Duncans WE: Theophylline Alters Vitamin D and Calcium Metabolism in Rats. Presented: American Society for Bone and Mineral Research - 10th Annual Scientific Meeting, New Orleans, LA, June 1988. (C)

McDermott MT: Tamoxifen Therapy for Painful Gynecomastia. Presented: The Endocrine Society - 70th Meeting, New Orleans, LA, June 1988.

Merenich J, Asp A, McDermott M, and Kidd GS: Adrenal Function in Patients with Early Asymptomatic Human Immunodeficiency Virus (HIV) Infection. Presented: The Endocrine Society - 70th Meeting, New Orleans, LA, June 1988. (C)

Merenich J, Georgitis W, and Kidd G: NIDDM Patients on Maximum Oral Hypoglycemics: Status at One Year Follow-up. Presented: The American Diabetes Association - 48th Meeting, New Orleans, LA, June 1988. (C)

(C) Direct result of approved registered protocol.

Merenich JA, Georgitis WJ, and Kidd GS: Reversible Hypogonadotropic Azoospermia in Congenital Adrenal Hyperplasia (CAH). Presented: American Fertility Society - 44th Meeting, Atlanta, GA, October 1988. (C)

Merenich JA, McDermott MT, and Kidd GS: Transient Isolated Trophoprivic Hypothyroidism in the Postpartum Period. Presented: 4th Annual Army Regional Meeting of the American College of Physicians. San Francisco, CA, October 1987. (C)

Perloff JJ, McDermott MT, Perloff KG, and Kidd GS: Risk Factors for Osteoporotic Hip Fractures. Presented: American Society for Bone and Mineral Research - 10th Annual Scientific Meeting, New Orleans, LA, June 1988. (C)

Simcic KJ, McDermott MT, and Kidd GS: Giant Cervical/Mediastinal Mass and Airway Obstruction Caused by Hemorrhage and Rupture of a "Functioning" Parathyroid Cyst. Presented: Adult Bone and Mineral Working Group, New Orleans, LA, June 1988.

Simcic KJ, and Sjoberg RJ: The Clonidine Suppression Test: A Review of its Utility in the Detection of Pheochromocytoma. The Endocrine Society - 70th Meeting, New Orleans, LA, June 1988. (C)

Sjoberg RJ, Merenich JA, O'Barr TP, and Kidd GS: Renal and Arterial Prostaglandin Production by Adrenalectomized Rats: Lack of a Contribution to Natriuresis and Hyperreninemia. Presented: The Endocrine Society - 70th Meeting, New Orleans, LA, June 1988. (C)

Sjoberg R, Swanson E, and Kidd G: Hypothyroid Rat Thromboxane and Prostacyclin Generation in Response to Low-dose Versus High-dose l-Thyroxine Replacement. Presented: 4th Annual Army Regional Meeting of the American College of Physicians, San Francisco, Ca, October 1987. (C)

General Internal Medicine Service

Ow CL, LeMar HJ, and Weaver MJ: Does Screenign Proctosigmoidoscopy Reduce Mortality From Colorectal Cancer? Presented: U.S. Army Regional ACP Meeting, San Francisco, CA, October 1987.

Weaver MJ, and Ow CL: Teaching Interviewing Skills: Getting Started. A Workshop. Presented: U.S. Army Regional ACP Meeting, San Francisco, CA, October 1987.

Weaver MJ: An Organized Approach to Ethical Dilemmas. Presented: U.S. Army Chaplains' Course "Introduction to Hospital Ministry", Aurora, CO, November 1987.

Rheumatology Service

Petros D, West S, and Nordstrom D: Seronegative Rheumatoid Arthritis: A Subset of RA with Microscopic Colitis. Presented: National American Rheumatism Association Meeting, Houston, TX, May 1988. (C)

(C) Direct result of approved registered protocol.

West S: Kikuchi' Disease. Presented: National American Rheumatism Association Meeting, Houston, TX, May 1988.

DEPARTMENT OF CLINICAL INVESTIGATION

Arena J, Sherman R, Bruno G, and Smith J: The Relationship Between Situational Stress and Phantom Limb Pain: Preliminary Analysis. Presented: 19th Annual Meeting Society for Applied Psychophysiology, Colorado Springs, CO, March 1988. (C)

Sherman R, Bruno G, Scotece G, Schwartz J, Hanson B, and Arena J: Importance of Differential Diagnosis in Patient Selection for Self-Control Based Treatments of Jaw Area Pain: Results of a Blind Study. Presented: 19th Annual Meeting, Society for Applied Psychophysiology, Colorado Springs, CO, March 1988. (C)

Stewart RS, and Gershwin LJ: Systemic and Secretory Antibody Responses to Sequential Bovine Respiratory Syncytial Virus Infection in Immunized and Non-Immunized Calves. Presented: Annual Meeting of the American Society for Microbiology, Miami Beach, FL., 1988.

Stewart RS, and Gershwin LJ: The Pathogenesis of Bovine Respiratory Syncytial Virus in Sequential Infections in Immunized and Non-Immunized Calves. Presented: Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, Reno, NV., 1988.

Stewart RS, and Gershwin LJ: The Role of IgE in the Pathogenesis of Bovine Respiratory Syncytial Virus in Sequential Infections in Immunized and Non-Immunized Calves. Presented: Annual Conference of Research Workers in Animal Diseases, Chicago, IL., November 1987.

DEPARTMENT OF MINISTRY & PASTORIAL CARE

AIDS for Professionals, The Next Step. "Guilt, Shame, and Grief" and "A Wellness/Wholeness Approach for the HIV+Patient." Presented: 3rd Annual Conference for Practitioners, New York City, April 1988. (C)

HIV/AIDS Update/ A Psycho-Social-Spiritual Model of Wellness in the HIV+Patient. Presented: Chaplain Training Conference, Health Services Command, San Antonio, Texas, May 1988. (C)

DEPARTMENT OF NURSING

Geniton D: A Comparison of the Hemodynamic Effects of Labetalol and Sodium Nitroprusside in Patients Undergoing Carotid Endarterectomy. Presented: Phyllis D. Vehonick Nursing Research Course, Washington, DC, April 1988.

Hasbargen BJ: CAPD in the Diabetic Patient. Presented: Baxter's CAPD Certification Program, Los Angeles, Ca, May 1988.

(C) Direct result of approved registered protocol.

Krom F: Nursing Diagnosis and the Normal Newborn. Presented: Nurses' Association of the American College of Obstetricians and Gynecologists. Northern Colorado Chapter, Estes Park, CO, October 1987.

DEPARTMENT OF PATHOLOGY

Brooke JD, Fitzpatrick JE, and Golitz LE: Papillary Mesenchymal Bodies: A Histologic Finding Useful in Differentiating Trichoepitheliomas From Basal Cell Carcinomas. Presented: Colorado Society of Clinical Pathology Annual Resident Presentations, Denver, CO, March 1988. (C)

Vishnu B, and Reddy V: From Stern Cell to Functioning Blood Cell. CACMLE Course HE*331. Presented: CACMLE Center, Denver, CO, January 1988.

Vishnu B, and Reddy V: Update on Leukemia/Lymphoma Cytochemistry and Markers: A Pathologist Perspective. Presented: Pediatric Oncology Group Meeting, Orlando, FL, April 1988. (C)

Vishnu B, Reddy V, and Ownbey JL: Enhanced Visualization of Immunogold-Silver Particles by Modified Modulation Contrast Microscopy. Presented: Eight International Congress of Histochemistry (Histochemical Society of American), Washington, DC, August 1988. (C)

DEPARTMENT OF PEDIATRICS

Brantner L, and Slover RH: A Study Investigating the Use of Clonidine in the Treatment for Constitutional Short Stature. (C)

Carter BS, Merenstein GB, and Murphy JR: Prospective Validation of a Morbidity Index. Presented: Society for Pediatric Research, Washington, DC, April 1988.

Carter BS, Merenstein GB, and Murphy JR: Prospective Validation of a Morbidity Index: Presented: 13th Annual Conference on Neonatal/Perinatal Medicine, District VIII Section on Perinatal Pediatrics, Scottsdale, AZ, May 1988.

Carter BS, Merenstein GB, and Murphy JR: Prospective Validation of a Morbidity Index: Presented: 8th Annual Conference on Military Perinatal Research, Aspen, CO, July 1988.

Humberd QA: Non-Organic Failure to Thrive - Use of Team Approach. Presented: The Annual 7th Medcom Pediatrics Course, Heidelberg, West Germany, December 1987.

Humberd QA: Behavioral Assessment and Counseling for the Primary Physician. Presented: The Annual 7th Medcom Pediatric Course, Heidelberg, West Germany, December 1987.

Slover RH: Reactive Hyperemia as a Function of Control and Duration of Type I Diabetes.

(C) Direct result of approved registered protocol.

Slover RH: A Study Comparing the Growth Hormone Response in Growth Hormone Deficient Children to Two Commercially Available Preparations of Growth Hormones.

PHARMACY SERVICE

Dydek GJ: Nuclear Pharmacy and the Potential Role of the Pharmacy Technologist. Presented: Colorado Society of Hospital Pharmacists Annual Meeting, Denver, CO, November 1987.

Dydek GJ, Blue PW, Thompson G, and McKinstry ER: Application of a Pharmacy Service Computer System to Nuclear Pharmacy. Presented: Ralph D. Arnold Pharmaceutical Services Management Conference, San Antonio, TX, May 1988.

DEPARTMENT OF RADIOLOGY

Blue PW: The Spectrum of Renal Nuclear Medicine. Presented: Syncor Lecture Series, Denver, CO, December 1987.

Hopper K, Nieves N, Meilstrum J, and Ghaed N: Imaging Anomalies of the Gallbladder. Presented: December 1987 Radiological Society of North America Meeting.

Hopper K, Moser R, Haseman D, Sweet D, and Krandsorf M: Osteosarcomatosis: Metastatic Variant of Osteosarcoma. Presented: December 1987 Radiological Society of North America.

Seibel D, Hopper K, and Ghaed N: Unilateral Breast Edema Mimicking Inflammatory Carcinoma. Presented: Annual Convention of American Osteopathic College of Radiology, October 1987.

Yakes KD, Haas D, Bourne E, and Brown S: Angioplasty of the Infrarenal Abdominal Aorta. Presented: 1987 Radiological Society of North America Meeting; 1988 Rocky Mountain Radiological Society Meeting.

SOCIAL WORK SERVICE

Neptune C: Crisis Intervention with Victims of Middle East Terrorism. Presented: U.S. Army Medical Department Social Work Course, San Antonio, TX, May 1988.

Neptune C: Mental Health/Medical Team Intervention in Support of Military Hostage Retrieval Missions. Presented: DOD Uniformed Nurse Clinician Symposium, Norfolk, VA, June 1988.

Rogers DR: The Role of the 91G in a MEDCEN Emergency Room. Presented: Senior Behavioral Science Specialist Course, Ft. Sam Houston, TX, May 1988.

(C) Direct result of approved registered protocol.

DEPARTMENT OF SURGERY

General Surgery Service

Conarro PA, Schoelkopf L, and Clark JR: Venous Thromboembolic in the Obese Patient: Assessment of Risk In Vitro Before and After Surgically Induced Weight Loss. Presented Gary Wratten Surgical Symposium, Bethesda, MD, March 1988.

Crawford GJ, Cleland BP, and Clark JR: Parathyroid Adenoma Localization Using the Thallium-Technetium Perfusion Scan. Presented: Colorado Chapter of the American College of Surgeons Meeting, Colorado Springs, CO, May 1988.

Culbertson GR, Conarro PA, Clark JR, Hovenga TL, and Schoelkopf L: Gastric Partitioning with Stapled Gastrogastrostomy for Morbid Obesity: Presented: American College of Surgeons Meeting, San Francisco, Ca, October 1987.

Culbertson GR, Cleland BP, and Clark JR: Management of Breast Cancer Presenting as an Axillary Mass. Presented: Colorado Chapter of the American College of Surgeons Meeting, Colorado Springs, CO, May 1988.

Herrold JW, Cleland BP, and Clark JR: Malignant Fibrohistiocytoma. Presented: Gary Wratten Surgical Symposium, Bethesda, MD, March 1988.

Hollis HW, Rutherford RB, Crawford GJ, Cleland BP, Marx WH, and Clark JR: Abdominal Aortic Aneurysm Repair in Patients with Pelvic Kidney. Presented: Annual Military Vascular Seminar and Chesapeake Vascular Society Meeting, Bethesda, MD, December 1987.

Hovenga TL, Clark JR, Moncrief C, and Fall S: Muscle Surface pH Monitoring in Patients Undergoing Coronary Artery Bypass Grafting. Presented: Gary Wratten Surgical Symposium, Bethesda, MD, March 1988.

Marx WH: Prevention of Deep Venous Thrombosis and Pulmonary Embolism. Presented: American College of Osteopathic Surgeons In-Depth Review, Boston, MA, June 1988.

Marx WH: The Structure and Function of a Nutritional Support Service. Presented: American College of Osteopathic Surgeons In-Depth Review, Boston, MA, June 1988.

Thrasher, JB, Cleland BP, and Clark JR: Surgery for Pulmonary Metastases From Renal Cell Carcinoma: Army Experience From 1977-1987. Presented: Gary Wratten Surgical Symposium, Bethesda, MD, March 1988.

Neurosurgery Service

Casey KF: Invitro Chemotherapy. Presented: American College of Surgeons, Colorado Springs, CO, May 1988.

(C) Direct result of approved registered protocol.

Casey KF: Intraoperative Evoked Potential Monitoring. Rocky Mountain Neurosurgical Society Meeting, Lake Tahoe, Nevada, June 1988.

Ophthalmology Service

Enzenauer RW, and Mauldin WM: Ocular Injuries Associated with Boxing in the US Army, 1980-1985. Presented: 82nd Annual Scientific Assembly of the Southern Medical Association, Section on Ophthalmology, New Orleans, LA, November, 1988.

Enzenauer RW, Cornell FM, Brooke JD, and Butler CE: Nocardia asteroides Keratitis: The First Case Associated with Soft Contact Lens Wear and a Review of the Ocular Nocardiosis. Presented: Ophthalmology Section of the 81st Annual Scientific Assembly of the Southern Medical Association, San Antonio, TX, November 1987.

Enzenauer RW, Cornell FM, Brooke JD, and Butler CE: Nocardia asteroides Keratitis: The First Case Associated with Soft Contact Lens Wear and a Review of the Ocular Nocardiosis. Presented: Annual Meeting of the Ocular Immunology and Microbiology Group, Dallas, TX, November, 1987.

Enzenauer RW, Montrey JS, Mauldin WM, and Enzenauer RJ: Boxing Injuries in the US Army, 1980-1985. Presented: Colorado Ophthalmological Society Annual Resident's Conference, Denver, CO, April 1988.

_____ Lid Injury and Repair on the Battlefield. Presented: Association of Military Plastic Surgeons, FAMC, April 1988. (C)

Orthopedics Service

Arena J, Sherman R, Bruno G, and Smith J: The Relationship Between Situational Stress and Phantom Limb Pain: Preliminary Analysis. Presented: 19th Annual Meeting of the Society for Applied Psychophysiology, Colorado Springs, CO, March 1988. (C)

Brugman JL: Adult Scoliosis - An Update. Presented: 16th Annual Symposium of Children's Orthopaedics, March 1988.

Colpini AW: Arthroscopic ACL Reconstruction: A Preliminary Report. Presented: Western Orthopaedic Association Meeting, Honolulu, HI, October 1988. (C)

Colpini AW: Arthroscopic ACL Reconstruction: A Preliminary Report. Presented: Society of Military Orthopaedic Surgeons Meeting, Williamsburg, Va, December 1988. (C)

Colpini AW: Surgical Treatment of the Symptomatic Accessory Tarsal Navicular Bone. Presented: Society of Military Orthopaedic Surgeons, San Diego, Ca, November 1987. (C)

(C) Direct result of approved registered protocol.

Hahn DB: Derotational Osteotomies of the Femur: Presented: 16th Annual Symposium of Children's Orthopaedics, FAMC, Aurora, CO, March 1988.

Hockenbury RT, Johns JC: A Biomechanical Comparison of Percutaneous versus Open Repair of Achilles Tendon Defects. Presented: Western Orthopaedic Society Annual Meeting, Honolulu, HI, 1988. (C)

Johns JC: Eaton Trapezium Implant Arthroplasty. Presented: Society of Military Orthopaedic Surgeons, San Diego, Ca, November 1987.

Johns JC: Congenital Finger Deformities. Presented: 16th Annual Symposium of Children's Orthopaedics, FAMC, Aurora, CO, March 1988.

McIntosh BR: Streptococcal Myositis: Is It Treatable? Presented: Society of Military Orthopaedic Surgeons, November 1987.

Ozaki JK: Treatment of the Painful Hip in Cerebral Palsy. Presented: Annual Pediatric Orthopedic Conference, FAMC, March 1988.

Perloff KG: CT-Myelogram versus MRI in Diagnosis of Lumbar Disc Disease. Presented: Society of Military Orthopaedic Surgeons, San Diego, CA, November 1987. (C)

Place HM: Hip Flexor Release in Patients with Cerebral Palsy: Minimum Five Year Follow-up. Presented: Society of Military Orthopaedic Surgeons, November 1987.

Pruitt A, Wilkerson RD, and Johns JC: Retrospective Analysis of Anterior Cruciate Ligament Reconstruction Done at FAMC 1982-1983. Presented: Society of Military Orthopaedic Surgeons, San Diego, CA, November 1987. (C)

Pruitt A, and Diermood T: Patterns of Tibial Fracture Healing. Presented: American Academy of Orthopaedic Surgeons, February 1988.

Sherman R, Bruno G, Scotece G, Schwartz J, Hanson B, and Arena J: Importance of Differential Diagnosis in Patient Selection for Self-Control Based Treatments of Jaw Area Pain: Results of a Blind Study. Presented: 19th Annual Meeting of the Society for Applied Psychophysiology, Colorado Springs, CO, March 1988. (C)

Otolaryngology Section (Speech Rehab)

Lowry-Romero F: Those Wonderful Swimming Laryngectomees, Video Demonstration. Presented: Colorado Speech-Language Hearing Association Annual Convention, Breckenridge, CO, April 1988.

(C) Direct result of approved registered protocol.

Snelling TM, Barrs DM, Merrill SM, Friel-Patti S, Gabbard SL, Northern JL, and Grose K: Current Trends in Treatment and Recent Advances in Research of the Child with Otitis Media: A Panel Discussion: Presented: Colorado Speech-Language Hearing Association Annual Convention, Breckenridge, CO, April 1988.

Snelling TM, and Ferrer-Vinent SK: The Otitis Media Clinic: A Multidisciplinary Approach to the Treatment of Otitis Media in Children. Presented: Military Audiology Conference, FAMC, Aurora, CO, May 1988.

Otolaryngology Service

Barrs DM, Lepore ML, and Carnel SB: Total Right Sided Nasal Obstruction, Secondary to Pyogenic Granuloma. Presented:

Blakeslee DB, Carnel SB, and Barnes M: Treatment of Radiation and Chemotherapy Induced Stomatitis. Presented:

Goldstein JL: Satisfaction Factor Part I and II. Presented: Iowa Hearing Aid Society Meeting, Des Moines, IA, August 1988.

Lanier DM, Clark J, and Simcic: Massive Mediastinal and Neck Presentation of Papillary Thyroid Cancer. Presented:

Lepore M: and Goldstein JL: Rehabilitative Aspects of the Hearing Impaired Geriatric Patient. Presented: American Academy of Otolaryngology - Head and Neck Surgery, Washington, DC, September 1988.

Plastic Surgery Service

Dr. Morton: Heel Reconstruction Using Flexor Digitorum Brevis. Presented: Annual Symposium of Military Plastic Surgery, April 1988.

Dr. Morris: Adjunctive Surgery for Craniofacial Tumors in Children. Presented: Annual Symposium of Military Plastic Surgery, April 1988.

Dr. Morton: Principles of Skin Grafting. Presented: ENT Symposium, June 1988.

Dr. Rich: Plastic Surgery of the Breast. American College of GYN, October 1987.

Dr. Rich: Reconstruction of Soft Tissue Injuries. Presented: ENT Symposium, June 1988.

Dr. Rich: Management of Maxillofacial Injuries. Presented: ENT Symposium, June 1988.

(C) Direct result of approved registered protocol.

Urology Service

Horne DW, et al: Unilateral Multicystic Kidney Disease in the Neonate: An Approach to Management. Presented: Society of Government Service Urologists Annual National Meeting, Washington, DC, November 1987.

Horne DW: The Fitzsimons Experience with Germ Cell Tumors, 1976-1987. Presented: Hawaii Urological Society, Honolulu, Hawaii, February 1988.

Quinones D, Wilson TM, Raife MJ, and Horne DW: Transrectal Ultrasound: An Eight - Month Review at Fitzsimons Army Medical Center. Presented: Society of Government Service Urologists Annual National Meeting, Washington, DC, November 1987.

Raife MJ: Melanoma Metastatic to the Bladder. Presented: Society of Government Service Urologists Annual National Meeting, Washington, DC, November 1987.

Thrasher B: Surgery for Pulmonary Metastases from Renal Cell Carcinoma: U.S. Army Experience from 1977-1987. Presented: Gary Ratton Seminar, Washington, DC, March 1988.

(C) Direct result of approved registered protocol.

DEPARTMENT OF MEDICINE

FAMC A.P.R (RCS MED300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 74/110 (3) Status: Completed

(4) Title: Reactive Hypoglycemia: An Analysis of Glucose-Insulin-Glucagon Interrelationships and Counter Hormonal Regulatory Factors

(5) Start Date: FY 71 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine (10) Associate Investigators:

(11) Key Words: Fred D. Hofeldt, MD
Insulin Coma Glucagon T.P. O'Barr, Ph.D.
Blood Glucose Annelie Shackelford, MT
Insulin Antagonists

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 399
e. Note any adverse drug reactions report to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of the hypoglycemic study is to continue to investigate in our clinic population the glucose-insulin-glucagon and prolactin interrelationships and the response of counter-regulatory hormones to hypoglycemic stress. This project is a continuation of the previous project initiated in 1969 at the University of California Medical Center, Moffatt Hospital, San Francisco, CA.

(16) Technical Approach: The clinical research protocol involves evaluation of control subjects and hypoglycemic patients to assess the interrelationships of beta cell and alpha cell responsiveness to oral and intravenous glucose administration. Based upon findings in controls and patients with disease states, a classification system has been proposed. The data have allowed for an understanding of the basic pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine, Endocrine Clinic, with the assistance of an assigned GS-5 Medical Technician to perform blood sampling and to assist during the testing. During the glucose tolerance test, the patient has an indwelling catheter for frequent sampling of blood glucose, and is continually monitored by a cardiac monitor system and blood sampling. After

(16) Technical Approach - continued:

glucose administration, blood insulins, glucagons, growth hormones, prolactins and cortisols are sampled and values are determined by a sensitive radioimmunoassay. Blood glucoses are assessed by the Ames Reflectance Meter immediately after sampling. The procedure is designed to provide a minimum of patient inconvenience in the performance of these well standardized procedures. Many normal individuals experience a low blood sugar state sometime after glucose administration, the significance of a low blood glucose state is observed by recording appropriate adrenergic symptoms at the nadir of the glucose and determining if there is a counter hormonal responsiveness to defend the stress of a low blood glucose state. This approach allows strict definition of bona fide reactive hypoglycemia, and clearly distinguishes it from the benign low blood glucose states.

(17) Progress: This protocol represents a long standing clinical investigation effort which has resulted in multiple presentations and publications. During the current year, however, no patients were admitted to the study. The data from a multitude of previous patients studied has been entered into a computer data base and is being analyzed by two former physicians from Fitzsimons, Dr. Fred Hofeldt and Dr. Michael Bornemann.

Presentations:

- (1) Hofeldt, F.D.: Reactive Hypoglycemia: Update 1980. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO 16 January 1980.
- (2) Sanders, L.R.: Reactive Hypoglycemia: Presented: Grand Rounds, University of Colorado Health Sciences Center, Denver, CO 13 March 1979.
- (3) Sanders, L.R.: Reactive Hypoglycemia. Presented: Medical Grand Rounds, Denver General Hospital, Denver, CO 15 May 1979.
- (4) Sanders, L.R.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Science Center, Denver, CO 11 April 1979.
- (5) Hofeldt, F.D.: Hypoglycemia. Grand Rounds, Delgado Amphitheater, Tulane Medical School Charity Hospital, New Orleans, LA 28 April 1982.
- (6) Hofeldt, F.D., and Scarlett, J.A.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO March 1982.

Publications:

- (1) Abrams, R., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, P.: Late Reactive Hypoglycemia in Hypothyroidism.
- (2) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal 76:30, 1979.
- (3) McCowen, K.D., Adler, R.A., O'Barr, T.P., and Hofeldt, F.D.: Clinical Implications of Flat Oral Glucose Tolerance Test. Military Medicine 144:177, 1979.
- (4). Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggins, J.T., and Eichner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients with Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia after Mixed Meals. Diabetes 30:465, 1981.
- (5) Sanders, L.R., Hofeldt, F.D., Kirk, M., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072, 1982.
- (6) Crapo, P.A., Scarlett, J.A., Kolterman, O., Sanders, L., Hofeldt, F.D., and Olefsky, J.: The Effects of Oral Fructose, Sucrose and Glucose in Subjects with Reactive Hypoglycemia. Diabetes Care 5:512, 1982.
- (7) Sanders, L.R., Hofeldt, F.D., Kirk, M.C., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072-1075, 1982.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 79/105 (3) Status: Ongoing

(4) Title: Breathing Pattern Effects on Steady-State DLCO
Measurement

(5) Start Date: November 1979 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael E. Perry, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Medicine/Pulmonary (10) Associate Investigators:
Neal B. Kindig, Ph.D.

(11) Key Words:
steady state DLCO
breathing pattern

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To experimentally confirm theoretically determined
corrections for breathing pattern during steady-state diffusion studies.

(16) Technical Approach: Breathing patterns with variations in inspiratory
and expiratory breath-holds will be performed while the subject undergoes
standard steady state diffusion measurement. If our approach is correct,
mathematical corrections for breathing pattern will result in a constant
value for diffusion capacity.

(17) Progress: Two subjects have participated in 5 studies of breathing
pattern effects. Variation from predicted effects was noted during pat-
terns with short apneustic indexes.

Presentations:

(1) Kindig, N.B.: DLCO Correction using PaCO Back Pressure Predicted from
Venous Blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO
1981.

Presentations - continued

(2) Perry, M.E.: Simplified Room Air (A-a) \dot{V}_O_2 Calculation. Presented: Carl E. Temple Pulmonary Symposium, Denver, CO 1981.

Publications:

(1) Perry, M.E., Browning, R.J., Kindig, N.B.: The Abbreviated Alveolar Air Equation Revisited. Chest 80:763-764, 1981.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/120 (3) Status: Ongoing

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis:
Investigations into the Frequency, Type and Mechanisms
of Carbohydrate Tolerance

(5) Start Date: 1981

(6) Est Compl Date: 1990

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators:

T.P. O'Barr, Ph.D., DAC

(11) Key Words:

Fred D. Hofeldt, COL, (Ret)

carbohydrate

Robert J. Sjoberg, CPT, MC

Hyperthyroidism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 11

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance test. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress: A new co-principal investigator has been assigned to this project, John A. Merenich, CPT, MC who is beginning his third year of Endocrinology fellowship. He has begun as of this date actively recruiting patients to try to finish up this study. Because the study is so complex and so time consuming, during the past year there was inadequate time available for the PI to continue this study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/121 (3) Status: Completed

(4) Title: An Evaluation of Pituitary and Thyroid Hormonal Response to a 4-hour Continuous and a Bolus Intravenous Infusion of TRH as a Useful Test of Thyroidal Functional Reserve

(5) Start Date: 1981 (6) Est Compl Date: 1989

(7) Principal Investigator: William J. Georgitis, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald S. Kidd, COL, MC Michael Bornemann, COL, MC

(11) Key Words: thyroid function tests
pituitary
thyroid hormones
Thyrotropin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 51
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objective of this study is to determine if the diagnosis of mild or subclinical hypothyroidism can be more clearly established by some integrated parameter reflecting both the pituitary and thyroidal reserve responses to intravenous thyrotropin releasing hormone.

(16) Technical Approach: Three groups of subjects will be evaluated in this protocol. Group 1 will consist of normal control patients; Group 2 will consist of patients with mild hypothyroidism diagnosed by an elevated TSH level but normal thyroid hormone levels; Group 3 will consist of patients with the thyroid clinic with high-normal TSH values and normal thyroid function tests, but who are clinical suspects of having mild hypothyroidism. The patients will undergo two TRH infusion tests in a random manner consisting of conventional bolus administration of 500 ug of TRH solution and the constant infusion of TRH over a 4-hour period of 500 ug of TRH diluted in normal saline and diffused at a rate of 2 ug/minute over the 4 hours using a Harvard infusion pump. The TSH values in the various groups of patients will be determined and statistically analyzed for differences between the groups.

(17) Progress: Thirty three patients and 15 controls have been studied to date. Further controls would be helpful, but in view of the advent of the new assays for TSH, we are preparing a manuscript based on the group studied to date.

Presentations:

(1) Bornemann, M.: Pitfalls in Mild Subclinical Hypothyroidism: Comparison of the TRH Bolus and Infusion. Submitted for Hugh Mahon Lectureship Award, FAMC, May 1983.

(2) Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. (Abst.) Clin. Res. 32:1, 1984.

(3) Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. Presented: Western Section, Western Meeting, Carmel, CA, February 1984.

(4) Bornemann, M. and Georgitis, W.: TRH Testing of Pituitary-Thyroid Axis in Early Hypothyroidism. Presented: Present Concepts in Internal Medicine, Army Regional Meeting ACP, 69-1, San Francisco, Ca, October 1986.

(5) Georgitis, W. and Bornemann, M.: TRH Testing: An Inadequate Confirming Test for Subclinical Hypothyroidism. Abstract submitted to Endocrine Society, 70th Meeting 1046:282, 1988.

(6) Georgitis, W., and Bornemann M: TRH Testing: An Inadequate Confirming Test for Subclinical Hypothyroidism. Presented: The Endocrine Society, 70th Meeting, New Orleans, LA, June 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald S. Kidd, COL, MC

(11) Key Words:
osteoporosis
bone density
calcitonin deficiency
thyroid hormone

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 32_____
d. Total Number of Subjects Enrolled to Date: 32_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, loose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and then normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - not calcium deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal controls. (SPA) single photon absorptiometry-distal and midradius - serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip-cross-sectionally.

(17) Progress: Initial cross-sectional study with SPA of the radius showed significantly lower bone density in the thyroid cancer group compared to the other 2 groups. Longitudinal 2 year data with SPA shows similar rates of radial bone loss among the 3 groups (no significant differences). Longitudinal 5 year data with SPA and cross-sectional data with DPA have not been analyzed yet.

Publications:

McDermott MT, Kidd GS, Blue P, Ghaed V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Gidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res 1(suppl. 1):352, 1986 (Abstract).

Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 81/118 (3) Status: Ongoing

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, LTC, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis
gonadotropins, pituitary

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress: One patient enrolled and studied. Her serum is frozen and awaiting assay.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 81/119 (3) Status: Ongoing

(4) Title: The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion

(5) Start Date: 1981

(6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, LTC, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 6

d. Total Number of Subjects Enrolled to Date: 16

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: In order to gain a better insight into the mechanism of gonadal dysfunction in hypothyroidism, the objective of this protocol is to study the effect of a thyrotropin releasing hormone (TRH) infusion on basal and gonadotropin releasing hormone (GnRH) stimulated gonadotropins in normal subjects.

(16) Technical Approach: Ten normal males will be studied with either a normal saline infusion or a TRH infusion. During these infusions, GnRH will be given as a bolus with measurement of appropriate hormone to determine interaction between releasing hormones.

(17) Progress: Sixteen subjects have been studied and the data analysis is complete. The TRH infusion produced a statistically significant augmentation of the FSH response (both peak and total integrated response) to GnRH, while the LH response was unaffected.

Publications: McDermott MT, Bornemann M, Sjoberg RJ, Walden T, Hofeldt F, Kidd GS: Effects of a continuous TRH infusion on GnRH stimulated gonadotropin secretion (Submitted for Publication, 1988).

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/104 (3) Status: Ongoing

(4) Title: The Effect of Tamoxifen on Gynecomastia

(5) Start Date: 1982

(6) Est Compl Date: 1989

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Fred D. Hofeldt, MD
Gerald S. Kidd, LTC, MC

(11) Key Words:
tamoxifen
gynecomastia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 12

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this protocol is to evaluate, in a double-blind placebo controlled prospective trial, the effect of Tamoxifen on males with gynecomastia and to characterize any co-existent hormonal changes.

(16) Technical Approach: A randomized, double-blind placebo controlled study of the effects of Tamoxifen therapy on idiopathic gynecomastia will be performed. Breast size will be assessed by photographs, palpation and measurement of tissue.

(17) Progress: Six subjects have completed the study, 5 have been lost to follow-up or dropped out and one is currently being studied. Compared to placebo, Tamoxifen significantly reduced pain in all stages of the disease, but reduced size only in those with stage 3 or less.

Publications: McDermott MT: Tamoxifen therapy for painful gynecomastia. Endocrinology 122 (Suppl):339 (127A), 1988 (Abstract).

Presentations: McDermott MT: Tamoxifen therapy for painful gynecomastia. Presented: 70th Meeting of the Endocrine Society, New Orleans, La, 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/114 (3) Status: Ongoing

(4) Title: Growth of Basal Cell Carcinoma Cells in Defined Medium
and Study of their Growth and Immunological
Characteristics

(5) Start Date: 1982

(6) Est Compl Date: 1990

(7) Principal Investigator:
Charles F. Ferris, CPT, MS

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:
Ronald W. Grimwood, MD
J. Clark Huff, MD
Richard A.F. Clark, MC

(11) Key Words:
basal cell carcinoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Growth and study of basal cell carcinoma cells
in culture.

(16) Technical Approach: The approach to culturing of basal cells has,
and will be the use of the media formulated by Dr. Ham's lab at the
University of Colorado in Boulder termed MCDB 153. We have been
successful to date in culturing normal cell carcinomas. This has
included an attempt utilizing fibronectin coated plates. We next will
be attempting growth utilizing basal cell tumors that we have success-
fully grown in nude mice. There is experimental evidence with other
tumors grown in nude mice to suggest that there is a greater success rate
of in vitro culture once the tumors have been grown in the animal model.

(17) Progress: The improved tissue culturing of keratinocytes have allowed
us to begin investigating the potential growth of BCC's.

Publications and Presentations: None

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/107 (3) Status: Ongoing

(4) Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma

(5) Start Date: 1984

(6) Est Compl Date: 1992

(7) Principal Investigator:
J. Ramsey Mellette, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators:
John Adnot, LTC, MC
Richard Gentry, LTC, MC

(11) Key Words:
retinoids
basal cell carcinoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 98

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Dry skin, chapped lips, myalgias.

(15) Study Objective: To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in high risk population; to examine possible side effects with long term administration of isotretinoin.

(16) Technical Approach: The study is a double-blind study with participants randomly assigned to the medication. Patients will take the med for three years and will be followed for a total of five years. Compliance side-effects and basal cells are very closely monitored.

(17) Progress: 86 patients remain on the study of the original 98. 3 patients are deceased, four patients have transferred to other study sites. 5 patients are off the study for miscellaneous reasons. 13 patients are off medication permanently, following adverse reactions consisting of back pain, macular degeneration, elevated triglycerides, mild cutaneous side effects, headaches, Steven-Johnson syndrome, others off medication permanently for the following reasons: Relocation to Europe, wanted to stop medication, afraid of long term side effects, miscellaneous medical problems, out of state and unable to follow on a regular basis. Ten patients are on permanent dose modification for the following reasons, mild cutaneous side effects, mild elevation of triglycerides, mild arthralgias, moderate cutaneous side effects and gastrointestinal side effects.

Publications:

Fitzpatrick JE, Mellette, JR: Geriatric Dermatology. In Geriatric Medicine: The Care of the Elderly Patient. First edition. W.B. Saunders Company.

Reed OM, Mellette JR, Fitzpatrick JE: Familiar Cervical Hypertrichosis with Underlying-Kypho-Scoliosis. Journal of the American Academy of Dermatology.

Presentations:

Flap Combinations for Large Facial Defects - American Academy of Dermatology Annual Meeting, San Antonio, Texas, December 1987.

Helpful Hints for Dermatological Surgery - Thirteenth Annual Tri-Services Dermatology Symposium, San Antonio, Texas, May 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/113 (3) Status: Ongoing

(4) Title: Growth of Human Keratinocytes

(5) Start Date: 1983

(6) Est Compl Date: 1990

(7) Principal Investigator:
Charles F. Ferris, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:

Ronald E. Grimwood, MD

(11) Key Words:

J. Clark Huff, MD

Phillip T. O'Barr, Ph.D., DAC

keratin

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Growth and study of human kertainocytes in culture and subsequent studies using athymicmice as an in vivo culture system.

(16) Technical Approach: The technical approach has been to grow keratinocytes obtained from newborn foreskins using serum-free media. A more successful approach has been to culture the cells in complete MCDB 153 media. A new mechanism of freezing the cells has commenced. The final phase of the study will include identifying specific proteins expressed by these cells and the presence of protein hormone receptors on the cell surfaces.

(17) Progress: Improved growth of cultures.

Publications:

Grimwood RE, Clark RAF, Baskin JB, Nielson LD, Ferris CF: Fibronectin is Deposited by Keratiocytes in the Basement Membrane Zone during Tissue Organization. Accepted for publication in Journal of Investigative Dermatol-ogy.

Grimwood RE, Ferris CF, Baskin JB, Nielson LD, Clark RAF: Fibronectin is Depostied by Keratinocytes in the Basement Membrane Zone during Tissue Or-ganization. J. Invest. Dermatol., Vol 86, #4, 479, 1986.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol W# 83/122 (3) Status: Ongoing

(4) Title: The Role of Food Allergy in the Pathogenesis of Migraine Headaches

(5) Start Date: 1983

(6) Est Compl Date: 1990

(7) Principal Investigator:
Thurman R. Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators:
Grant C. Olson, CPT, MC
Richard W. Weber, COL, MC

(11) Key Words:
migraine
food hypersensitivity
mediators

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 102
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To study the value of +6 allergy food skin test in directing and defining a diet which will cause a decrease in the frequency of migraine headaches in affected patients. To determine if immunological mediators can be detected in positive responders.

(16) Technical Approach: Approximately 100 patients with dx of migraine headaches who suffered 3 or more HA/month will keep a 1 month food diary/st diary. They will then be skin tested to 83 common foods and undergo an additional 1 mo diet eliminating suspected food, and skin test positive foods. Positive regimens will be studied with open chall. and double blind food challenge with immunologic mediators precursors.

(17) Progress: 102 patients studied thus far. 4 patients studied with immunologic mediator response.

Presentations:

(1) Vaughan, TR, Stafford, WW, Miller, BT, Weber, RW, Tipton, WR, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: American College of Allergists, Phoenix, AZ, January 1986.

(2) Vaughan, TR, Stafford, WW, Miller, BT, Tipton, WR, Weber, RW, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: Aspen Allergy Conference, Aspen, CO, July 1986.

(3) Vaughan TR, Stafford WW, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Presented: Southwest Allergy Forum, El Paso, TX, March 1987.

(4) Vaughan TR, Stafford WS, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Accepted for presentation American College of Allergists.

(5) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double-Blind, Long-term Followup Study. Presented: VI International Food Allergy Symposium, Boston, MA., November 1987.

(6) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double Blind, Long Term Followup Study. Presented: Harold S. Nelson Allergy Symposium, Aurora, CO., January 1988.

(7) Vaughan TR: Food and Migraine Headache. Presented: Keystone Allergy Conference, Keystone, CO., February 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: 1983

(6) Est Compl Date: 1990

(7) Principal Investigator:
Robert J. Sjoberg, MAJ, MC
Gerald S. Kidd, COL, MC
Thomas P. O'Barr, Ph.D., DAC

(8) Facility: FAMC

(9) Dept/Svc: MED/ Endocrine

(10) Associate Investigators:

(11) Key Words:
prostaglandin synthetic
hypothyroidism
water electrolyte balance, imbalance

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: No patients have been studied during the last fiscal year because of time constraints in relation to patient care and teaching activities and the performance of other research objectives. The investigators still feel that the hypothesis formulated within this protocol remains valid, and that the experimental methodology is good in terms of investigating that hypothesis. We would like to actively recruit patients within the next several months and so respectfully request that this protocol be continued.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 42-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 84/100 (3) Status: Ongoing

(4) Title: The Effect of Abnormal Thyroid States on the Metabolism of Theophylline and Methylprednisolone

(5) Start Date: 1984 (6) Est Compl Date: 1988

(7) Principal Investigator: Michael T. McDermott, LTC, MC
Ray Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:
Stanley J. Szeffler, MD
Harold S. Nelson, MD

(11) Key Words:
theophylline
methylprednisolone
hyperthyroidism
hypothyroidism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine whether hyperthyroidism and hypothyroidism result in alterations of theophylline and methylprednisolone metabolism.

(16) Technical Approach: Hypo- and hyperthyroid subjects are studied when thyroid function is abnormal and again when it is normal by studying the disappearance rate of theophylline and methylprednisolone from serum after bolus injections.

(17) Progress: 5 hyperthyroid and 2 hypothyroid patients have been studied. Theophylline metabolism is normal in hyperthyroidism and normal in hypothyroidism. Methylprednisolone metabolism is variable but essentially normal in hyper and decreased in hypothyroidism.

Presentations: Lavins B, Vaughan R, Szeffler S, Weber R, Nelson H: Effect of thyroid disease on metabolism of theophylline and methylprednisolone. Meetings of the American College of Allergists, Boston, Mass, October 1987.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 84/115 (3) Status: Ongoing

(4) Title: Heterotransplantation of Basal Cell Carcinomas to Nude Mice

(5) Start Date: 1984

(6) Est Compl Date: 1990

(7) Principal Investigator:
Charles F. Ferris, CPT, MS

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:
R.E. Grimwood, MD
J. Clark Huff, MD

(11) Key Words:
carcinoma, basal cell
transplantation
mice, nude

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To develop an in-vivo model of human basal cell carcinoma in the athymic mouse.

(16) Technical Approach: Basal cell carcinoma tissue obtained from excess tissue obtained from Moh's surgery is transplanted to a subcutaneous pocket created by a linear incision on the abdomen of the nude mouse. The mouse will have been splenectomized and transplantation is followed by weekly intraperitoneal injections of antilymphocyte serum. Tumor weight is taken before implantation and measurements of tumor size taken at weekly intervals. Autoradiography and immunofluorescent studies are performed at the time of tumor harvest as well as routine histology and tumor weight.

(17) Progress: No substantive progress this year. Renewed collaboration with Dr. Grimwood is anticipated.

Presentations:

(1) Grimwood RE, Johnson CA, Kramer LC, Mercill DB and Huff JC: Heterotransplantation of Human Basal Cell Epitheliomas in Nude Mice. Presented: SID Meeting, Washington, DC, May 1984.

(2) Grimwood, RE, Ferris CF, Nielsen LE, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude mice Produce and Deposit Fibronectin in the Extracellular Matrix. Presented: SID Meeting, Washington, DC, May 1985.

Publications:

(1) Grimwood RE, Harbel J, Clark RAF: Fibronectin in Basal cell Epitheliomas: Sources and Significance. Journal of Investigative Derm 82:145-149, 1984.

(2) Grimwood RE, Johnson CA, Ferris CF, Mercill DB, Mellette JR, Huff, JC: Transplantation of Human Basal Cell Carcinomas in Athymic Mice. Cancer

(3) Ferris, CF, Grimwood, RE, Kramer LC, Mercill DB and Huff JC: The Proliferating Cells of a Human Basal Cell Carcinoma are the Peripheral Palisaded Cells. Abst. Clinical Research, Vol. 33, No. 2, 636A, April 1985.

(4) Grimwood RE, Ferris CF, Mercill DB and Huff JC: The Proliferating Cells of Human Basal Cell Carcinoma are Located on the Periphery of Tumor Nodules. J. Investigative Derm. Clin. Res., Vol. 33 No. 4, Page 825A.

(5) Grimwood RE, Ferris CF, Mercill DB, Huff JC: The Proliferating Cells of Human Cell Carcinoma are Located on the Periphery of Tumor Nodules. J. Invest. Dermatol., Vol 86, No. 2, Pg 191-194, February 1986.

(6) Grimwood RE, Ferris CF, Nielson LD, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude Mice Produce and Deposit Fibronectin in the Extracellular Matrix. J. Invest. Dermatol., 87:42-46, 1986.

(7) Grimwood RE, Siegle RJ, Ferris CF and Huff JC: The Biology of Basal Cell Carcinomas - A Revisit and Recent Developments. J. Dermatol. Surg. Oncol., 12:8, August 1986.

(8) Siegle R, Grimwood R: Athymic Mice - A Model for the Transplantation of Human Basal Cell Carcinoma. J. Dermatol. Surg. Oncol., 12:6, June 1986, pp. 646.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 84/119 (3) Status: Ongoing

(4) Title: Treatment of Graves' Ophthalmopathy with Cyclosporin

(5) Start Date: 1984

(6) Est Compl Date: 1987

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC
Leonard Wartofsky, COL, MC

(8) Facility: FAMC
WRAMC
MAMC
BAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Anthony Truxal, CPT, MC

(11) Key Words:
eye disease
cyclosporin
prednisone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Cyclosporinte - Acne (1 pt.)
Prednisone - Acne, swelling (1 pt.)
Arthralgia on withdrawal (1 pt.)

(15) Study Objective: To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach: Patients with Graves' eye disease will receive a 3-week course of cyclosporine or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporine (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and B-2 microglobulin (urine).

(17) Progress: Two patients have been studied at FAMC. Neither improved on cyclosporine or prednisone. No toxicity noted. Two from WRAMC with acute Graves' ophthalmopathy have shown a good response. The results of other patients studied at other centers are not yet available to me.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/100 (3) Status: Ongoing

(4) Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III
SWOG #7804

(5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/101 (3) Status: Completed

(4) Title: Combined Modality Treatment for Stages III and IV
Hodgkin's Disease - MOPP #6, Phase III
SWOG #7808

(5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/102 (3) Status: Ongoing

(4) Title: Combined Modality Therapy for Breast Carcinoma, Phase III
SWOG #7827

(5) Start Date: 1979 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/114 (3) Status: Completed

(4) Title: Management of Disseminated Melanoma, Master Protocol,
Phase III
SWOG #8107

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Daniel Tell , MAJ, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/122 (3) Status: Ongoing

(4) Title: Treatment of Advanced Bladder Cancer with Preoperative
Irradiation and Radical Cystectomy vs. Radical Cystectomy
Alone, Phase III
SWOG #8221

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/132 (3) Status: Ongoing

(4) Title: Evaluation of Adjuvant Therapy and Biological Parameters
in Node Negative Operable Female Breast Cancer,
Intergroup Study
SWOG #8294

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 9
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WC#: 85/133 (3) Status: Ongoing

(4) Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation
Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III
SWOG #8300

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
drug therapy (11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/136 (3) Status: Ongoing

(4) Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER
Negative Stage II Carcinoma of the Breast, Phase III
SWOG #8313

(5) Start Date: 1974 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/139 (3) Status: Ongoing

(4) Title: National Intergroup Protocol for Intermediate Thickness
Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Margins
(2 vs 4 cm) Around the Primary Melanoma and Evaluation
of Elective Regional Lymph Node Dissection
SWOG #8393

(5) Start Date: 1983 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/141 (3) Status: Ongoing

(4) Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II
SWOG #8411

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/142 (3) Status: Ongoing

(4) Title: Evaluation of Tamoxifen in Unresectable and Refractory
Meningiomas, Phase II
SWOG #8415

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
drug therapy (11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (1 SCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/147 (3) Status: Ongoing

(4) Title: HLA and Gm Genes in Systemic Lupus Erythematosus
Antibody Expression

(5) Start Date: 1985

(6) Est Compl Date: 1988

(7) Principal Investigator:
Christopher LeSueur, MD
Sterling West, MD

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology

(10) Associate Investigators

(11) Key Words:
lupus erythematosus, systemic
HLA antigens

Moses Shanfield, Ph.D.

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 27

d. Total Number of Subjects Enrolled to Date: 126

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if patients with systemic lupus erythematosus have increased prevalence of any HLA and Gm genes as it relates to their autoantibody expression compared to a control group.

(16) Technical Approach: After patient education and consent form is signed, the patient has eight tubes of heparinized blood drawn for HLA and Gm typing. The patient's clinical symptoms, signs and other laboratory parameters are collected according to protocol and correlated with the patient's HLA and Gm typing.

(17) Progress: We have collected an additional 27 patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/157 (3) Status: Ongoing

(4) Title: Phase III Study to Determine the Effect of Combining
Chemotherapy with Surgery and Radiotherapy for Resectable
Squamous Cell Carcinoma of the Head and Neck
SWOG #8590

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
chemotherapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/158 (3) Status: Ongoing

(4) Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or
Levamisole Plus 5-Fluorouracil as Surgical Adjuvant
Treatment for Resectable Adenocarcinoma of the Colon,
Phase III-Intergroup
SWOG #8591

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/163 (3) Status: Ongoing

(4) Title: The Effect of Theophylline and Nifedipine on Hormone Secretion

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael McDermott, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, COL, MC

(11) Key Words:
theophylline
nifedipine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this protocol are to study the effect of theophylline and nifedipine on hormone secretion patterns in order to probe the intracellular mechanisms of hormone secretion and to better understand the effects of these medications on endocrine function tests.

(16) Technical Approach: Subjects will have a combined pituitary stimulation study (TRH, GnRH and ACTH) on 3 occasions: control period, during a theophylline infusion, after 2 days of taking nifedipine. Basal and peak hormone responses to the stimulating hormones will be compared among the 3 periods.

(17) Progress: 10 subjects have been studied. Theophylline enhances and nifedipine impairs the cortisol response to ACTH. The data for TSH, T3, prolactin, LH and FSH are not yet analyzed.

Publications: McDermott MT, Walden T, Bornemann M, Sjoberg RJ, Hofeldt F, Kidd GS: The effects of theophylline and nifedipine on ACTH stimulated adrenal cortisol secretion (accepted for publication).

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/165 (3) Status: Ongoing

(4) Title: An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae

(5) Start Date: 1985

(6) Est Compl Date: 1988

(7) Principal Investigator:
R.W. Weber, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:
pollen
hypersensitivity
allergens

R. Ledoux
Bernard L. Crosby, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate patterns of cross allergenicity among pollens of the weed families, Chenopodiaceae and Amaranthaceae.

(16) Technical Approach: Evaluation of cross reactivity using human antigen and ELISA in inhibition, rabbit antisera and CIE, CRIE. Allergen characterization using PAGE, IEF, and Western Blot.

(17) Progress: Three subprotocols completed and presented, now being prepared for publication. Search for effective adjuvant to replace CFA successfully. Rabbit protocol can therefore continue.

Presentations: Goodman DL, Ledoux RA, Weber RW: Comparison of Adjuvant Systems in the Production of Pollen Antisera in Rabbits. Presented: American Academy of Allergy & Immunology Annual Meeting, Washington, DC, February 1987.

Muggleberg, ML, Ledoux RA, Weber RW: Cross-Allergenicity of Western Prairie Grasses Evaluation by ELISA Inhibition. Presented: American Academy of Allergy & Immunology, Anaheim, CA., March 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (F SCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/166 (3) Status: Ongoing

(4) Title: Colon Inflammation in Reiter's Syndrome: Response to Sulfasalazine. Results in a Controlled Study

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:

David Nordstrom, MD
Sterling West, MD
Peter Andersen, MD

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology

(10) Associate Investigators

(11) Key Words:

Reiter's disease
reactive arthritis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 60

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To see if patients with idiopathic Reiter's syndrome have colon inflammation and to see (in double-blinded fashion) if this responds to Sulfasalazine.

(16) Technical Approach: Colonoscopy with biopsy is performed on Reiter's patients and controls (patients with inflammatory arthritis that is not Reiter's).

(17) Progress: Patients and controls continue to be added to the protocol. Although numbers are still small, patients with Reiters seem to have a favorable response to Sulfasalazine, and their microscopic inflammation improves as well. A small number of new patients (5) have been added this FY and patients treated with Sulfasalazine continue to be followed closely for 6-8 months. A new manuscript is in preparation.

Publication: Nordstrom DM, West SG, Freeman S, Reddy V: HLA-B27 Postivie Enterogenic Ractive Arthritis: Respone of Arthritis and Microscopic Colitis to Sulfasalazine. Arthritis Rheum. 30:524, 1987.

Presentation: HLA-B27 Positive Enterogenic Reactive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Presented: Nat. Am. Rheu. Ass., Washington, DC, July 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/167 (3) Status: Ongoing

(4) Title: The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators

(11) Key Words:
thyroid diseases
thyroid function tests
thyroid gland

William J. Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC
Tony L. Walden, CPT, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 11
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effect of age on the perchlorate discharge test in individuals with thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without thyroid disease by history, physical examination and lab evaluation will be studied. A perchlorate test will be performed in Nuclear Medicine.

(17) Progress: One new patient was studied during FY 83 without complications or difficulties. The data so far analyzed appears to be negative in terms of demonstrating an abnormal perchlorate discharge test in older patients without known thyroid disease. However, during FY 89, we need to study several more patients to finish up this protocol. Request continuation of the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/173 (3) Status: Completed

(4) Title: The Effects of Gonadal Steroids on Arachidonic Acid
Metabolites and Angiotensin Converting Enzyme Activity
in Female Rats

(5) Start Date: Nov 85

(6) Est Compl Date: FY 87

(7) Principal Investigator:
Tony L. Walden, CPT, MC
William J. Georgitis, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael T. McDermott, MAJ,
Michael Bornemann, COL, MC

(11) Key Words:
prostaglandins
steroids

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 4 Aug 86 b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 48 rats
d. Total Number of Subjects Enrolled to Date: 48 rats
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The investigation will examine the effects of sex
steroids on arachidonic acid metabolites and angiotensin converting enzyme
activity in female rats.

(16) Technical Approach: This study examines the effects of oophorectomy
and sex steroids on serum and lung ACE activity and prostaglandins in
female rats. The rats were divided into four groups - shams, castrates,
castrates treated with estradiol, and castrates treated with progesterone
delivered by Alzet osmotic minipumps.

(17) Progress: No alterations in prostaglandins were found. ACE results
are to be incorporated in a report with results found from a previous study
in male rats. Further investigation of prostaglandins could be done in
this area but should probably involve different methodology. Protocol is
completed this FY.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/167 (3) Status: Ongoing

(4) Title: The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators

(11) Key Words:
thyroid diseases
thyroid function tests
thyroid gland

William J. Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC
Tony L. Walden, CPT, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 11
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effect of age on the perchlorate discharge test in individuals with thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without thyroid disease by history, physical examination and lab evaluation will be studied. A perchlorate test will be performed in Nuclear Medicine.

(17) Progress: One new patient was studied during FY 88 without complications or difficulties. The data so far analyzed appears to be negative in terms of demonstrating an abnormal perchlorate discharge test in older patients without known thyroid disease. However, during FY 89, we need to study several more patients to finish up this protocol. Request continuation of the protocol.

Publications and Presentations: None

Presentations:

Georgitis W, Walden T, Noble S, McCullen A, Kidd GS: Oophorectomy and Sex Steroids Affect Angiotensin-Converting Enzyme Activity. Presented: Endocrine Society, Anaheim, CA, June 1986.

Walden TL, Georgitis WJ, Noble S, and Kidd GS: Oophorectomy and Sex Steroids Affect Angiotensin-Converting Enzyme Activity. Presented: Colorado Associate's Meeting, American College of Physicians Meeting, Denver, CO, April 1986.

Publications:

Georgitis W, Walden T, Noble S, McCullen A, and Kidd GS: Oophorectomy and Sex Steroids Affect Angiotensin-Converting Enzyme Activity. Endocrinology 118 (Suppl 1) 157 (Abs 506), 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 -s amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/174 (3) Status: Ongoing

(4) Title: Evaluation of Combination Chemotherapy Using High Dose
ARA-C in Adult Acute Leukemia and Chronic Granulocytic
Leukemia in Blastic Crisis, Phase III
SWOG 8326/27

(5) Start Date: 1983

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Daniel Tell, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in
the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/10X-001 (3) Status: Ongoing

(4) Title: Feasibility Study to Determine if Estrogen and Progesterone Affect in-vitro Growth of Cultured Malignant Melanoma (MM) Cell Lines

(5) Start Date: 1986

(6) Est Compl Date: 1990

(7) Principal Investigator:
James Fitzpatrick, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators

Donald B. Mercill, DAC

(11) Key Words:

Thomas P. O'Barr, DAC

malignant melanoma

Charles F. Ferris, CPT, MS

receptors

estrogen

progesterone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether malignant melanoma cell lines previously obtained and stored (frozen) have estrogen and progesterone receptors. If receptors can be identified, then a full scale protocol can be undertaken to determine if estrogen and progesterone have an effect on cell growth.

(16) Technical Approach: Malignant melanoma cells lines currently stored in the Cell Physiology Service will be grown to confluence. Specific binding will be characterized utilizing a dextran-coated charcoal technique.

(17) Progress: Control receptor analysis is completed, investigation has commenced on possible positive cell lines.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/100 (3) Status: Ongoing

(4) Title: Assessment of Nonspecific Decrease in Skin Test Reactivity
During Immunotherapy

(5) Start Date: 1986

(6) Est Compl Date: 1989

(7) Principal Investigator:
Richard W. Weber, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

James S. Brown, LTC, MC

(11) Key Words:
skin test
immunotherapy

Bernard L. Crosby, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: 6

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether there is a nonspecific decrease in skin test reactivity to unrelated extracts during immunotherapy.

(16) Technical Approach: Patients placed on immunotherapy will receive periodic titrated skin tests to allergens in the treatment sets, as well as allergens not in the treatment sets, as well as skin tests to histamine and compound 48/80.

(17) Progress: In progress, active, 5 are completed. The consent form is updated.

Publications and Presentations: None at present.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/103 (3) Status: Ongoing

(4) Title: Evaluation of Low Dose Ara-C versus Supportive Therapy
Alone in the Treatment of Myelodysplastic Syndromes
(ECOG EST 4483)
SWOG #8592

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/104 (3) Status: Terminated

(4) Title: Comparison of Quantitative Immuno-electrophoresis (QIE),
Skin Prick Testing, RAST Inhibition, and ELISA Inhibition
(EI) Methods for Determination of Allergen Extract
Potency

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:
William K. Dolen MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:
immuno-electrophoresis
enzyme-linked immunosorbent assay

Robert L. Ledoux, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To examine the correlation between several methods by
which an allergen extract of unknown potency can be compared to a reference
extract.

(16) Technical Approach: Sera will be collected from persons allergic to
cat, artemesia, and used to assess the potency of allergic extracts by EAST
(ELISA) inhibition.

(17) Progress: No progress in past year. Request termination of protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/105 (3) Status: Completed

(4) Title: Immune Response in Dialysis Patients Receiving
Desferrioxamine

(5) Start Date: 1986 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

James A. Hasbargen, MAJ, MC

(9) Dept/Svc: MED/IntMed/Neph (10) Associate Investigators
Robert Hull, MD

(11) Key Words:
dialysis
deferrioxamine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: This study is designed to assess immunologic
parameters in a cohort of 12 dialysis patients before, during, and at the
completion of desferrioxamine therapy. Serial serum trace element deter-
minations will be made before and at the completion of therapy.
Study was amended by COL Shetler at the time of approval to include
controls.

(16) Technical Approach: We are measuring T lymphocytes subsets and mitogen
stimulation using Con A and PHA.

(17) Progress: No further enrollement. No adverse effects, study is com-
pleted.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/107 (3) Status: Ongoing

(4) Title: In-Vitro Drug Sensitivity Utilizing the Guinea Pig Airway Smooth Muscle Model

(5) Start Date: 1986

(6) Est Compl Date: 1988

(7) Principal Investigator:
T. Ray Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators
Richard W. Weber, COL, MC
Anthony R. Henry, LTC, MC

(11) Key Words:
drug sensitivity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We have previously demonstrated in the guinea pig tracheal model the development of subsensitivity to beta-adrenergic agonists, it would now be useful to have an animal model to study the effect of B-agonists and anticholinergic meds on B-blockade induced tracheal contractions.

(16) Technical Approach: In-vivo blockade of B receptors in guinea pigs with propranolol will be achieved with either po ingestion or serial injections. Subsequently in in-vitro studies we will excise tracheal ring segments, induce contraction with methylcholine and/or histamine and study the comparative effects of an anticholinergic drug and a B-agonist.

(17) Progress: Completed work with stability studies of methylcholine and atropine methylnitrate. Will hopefully begin studies of B-blockade in Oct-Nov 1988. (Drs. Henry, Vaughan and Weber)

Presentations: American College of Allergist National Meeting, 1986

Publications: Ann. All. 56:117-119, 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/108 (3) Status: Ongoing

(4) Title: Investigation of Alterations in Angiotensin Converting Enzyme Activities Resulting from Different Prolactinemic States in the Male Sprague-Dawley Rat

(5) Start Date: 1986

(6) Est Compl Date: FY 87

(7) Principal Investigator:
William J. Georgitis, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Gerald S. Kidd, COL, MC
Tony L. Walden, CPT, MC
Lawrence E. Jones, DAC
Charles F. Ferris, CPT, MS
Ellen Swanson, DAC
Sharon Noble, DAC
Arnold Asp, MAJ, MC

(11) Key Words:
angiotensins
prolactinemic states

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 7 Jan 86 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 60 rats
d. Total Number of Subjects Enrolled to Date: 60 rats
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: This experiment is designed to investigate whether the activity of angiotensin converting enzyme in male Sprague-Dawley rats is altered by prolactin.

(16) Technical Approach: Four groups of rats were treated with vehicle, pergolide, metoclopramide, and metoclopramide plus testosterone delivered by Alzet osmotic minipumps for two weeks.

(17) Progress: A treatment effect was achieved but ACE and parameters of gonadal status were unaltered by the different states of prolactin achieved by the drugs. Further work may be done on frozen specimens in storate.

Publications:

(1) Georgitis W., Asp., Swanson E., Noble S., and Kidd G: Angiotensin Converting Enzyme Activity in Different Prolactinemic States. (Abstract) Clinical Res. 35(1):119A, 1987.

(2) Georgitis W., Swanson E., and Kidd G.: Lack of Effect of Drug Induced Prolactin Degrangements on Male Rat Gonadal Axis. Present Concepts in Internal Medicine Postgraduate Course and 4th Annual ACP Army Scientific Meeting, San Francisco, Ca., October 1987.

(3) Swanson E., Noble S., and Georgitis W.: Sustained Prolactin Derangements Fail to Alter Male Rat Gonadal Axis. The Endocrine Society, 70th Meeting. Abstract 631:629, New Orleans, La., June 1988.

Presentations:

(1) Georgitis W, Swanson E, and Kidd G: Lack of Effect of Drug Induced Prolactin Derangements on Male Rat Gonadal Axis. Presented: 4th Annual ACP Army Scientific Meeting, San Francisco, CA, October 1987.

(2) Swanson E, Noble S, and Georgitis W: Sustained Prolactin Degrangements Fail to Alter Male Rat Gonadal Axis. Presented: 70th Annual Meeting of the Endocrine Society. New Orleans, La, June 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/109 (3) Status: Ongoing

(4) Title: The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:
John Merenich, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators

Gerald S. Kidd, LTC, MC

Michael E. Perry, COL, MC

Michael T. McDermott, MAJ, MC

Fred Negron, CPT, MC

Peter Blue, LTC, MC

Nasser Ghaed, COL, MC

(11) Key Words:

calcium

vitamin D rifampin

vitamin D deficiency

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 7

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The purpose of this study is to see if INH therapy alters vitamin D and/or calcium metabolism in a significant manner. This may then lead to further evaluation to determine if patients would benefit from vit D or calcium supplementation while receiving INH therapy.

(16) Technical Approach: Ten to 20 patients will be begun on INH therapy for their recent PPD conversion. Determinations of Vit D (25-OH, 1,25-OH), serum calcium, PTH, 24-hour urine calcium and SMA-18 are drawn at baseline, 2 weeks, 6 and 9 months. Bone densitometry is obtained before and after therapy.

(17) Progress: Seven patients have been entered in the study as of this date. Once again key investigators have departed Fitzsimons making enrollment and follow-up of patients difficult. The sole principal investigator now (CPT Menerich) has re-established contact with the pulmonary clinic in order to facilitate patient recruitment. Further, CPT Menerich has contacted the original protocol developer, MAJ A. Asp, now stationed at Eisenhower AMC. MAJ Asp plans to submit the protocol to his local IRC, thus making the study a two-center venture. Request continuation of the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/110 (3) Status: Ongoing

(4) Title: The Use of Standardized Allergen Extracts in Prick Skin Testing

(5) Start Date: 1986

(6) Est Compl Date: 1988

(7) Principal Investigator:
William K. Dolen, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:

allergen extracts
skin test

Robert Ledoux, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 16

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine the optimum concentration of standardized allergen extracts for routine use in prick skin testing.

(16) Technical Approach: Atopic and nonatopic patients will receive skin testing with standardized and nonstandardized extracts in order to determine whether the standardized extracts differ from the conventional ones in potency and incidence of false positive reactions.

(17) Progress: Work in progress, active. Eleven nonatopic patients have been tested, and 5 atopic subjects. Anticipate completion by July, 1988. New Fellows to be assigned to protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HTLV-III Infection and Disease in a
United States Military Community

(5) Start Date: 1986

(6) Est Compl Date: 1992

(7) Principal Investigator:
Shannon M. Harrison, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Inf Dis

(10) Associate Investigators

Leo A. Andron, LTC, MC

(11) Key Words:
HIV virus

Roland N. Hannon, PA-C, CW3 (RET)

Richard W. Burris, PA-C, GS12

Robert H. Gates, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 9/86 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 75

d. Total Number of Subjects Enrolled to Date: 300

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough understanding of the
pattern of disease progression and clinical course in individuals with
documented HTLV-III infection within the general military population in-
cluding active duty, dependents, and retirees. This will provide critical
information for clinical and administrative management of patients.

(16) Technical Approach: Collect data on all patients who are required to
be staged by DA directives and any who request staging.

(17) Progress: As noted an additional 75 patients have been added to the
Natural History Study in the previous year. However, there is about a 25%
attrition rate in terms of new patients added that dropped from follow-up
either through death, moving to another facility or being separated from
military beneficiary status. The data to date would suggest that 30% of
all persons followed more than 12 months will progress at least 1 Walter
Reed stage. (This information of sensitive nature for Official Use Only).

Presentations: To Army ID & PM group, San Antonio, Texas, January 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/115 (3) Status: Ongoing

(4) Title: A Prospective Evaluation of Neuropsychiatric Sequelae
of HTLV-III Disease

(5) Start Date: 1986 (6) Est Compl Date:

(7) Principal Investigator: William Clayton, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: of Medicine (10) Associate Investigators
Shannon M. Harrison, LTC, MC
Richard G. Grape, SSG, USA
Leo A. Andron, LTC, MS
Rowland N. Hannon, PA-C CW3 RET

(11) Key Words:
human immunodeficiency virus
neuropsychological tests

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 43
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To determine the prevalence and progression of
neuropsychiatric disease in an HTLV-III positive military population.

(16) Technical Approach: Patients have been enrolled in the Neurop-
sychiatric Protocol from the umbrella Protocol dealing with Natural History
of HTLV-III Disease. This allocation has been random except for expecta-
tion of good follow up. There have been no significant changes in overall
protocol approach.

(17) Progress: Twenty-five individuals have been lost to follow-up due to
separation from the service and relocation from this geographic area. No
other patients being enrolled.

Presentations:

Haburchak, D.R.: A Prospective Evaluation of Neuropsychiatric Sequelae of
HTLV-III Disease. Presented: U.S. Army AIDS Conference, Arlington, VA,
September 1986.

Haburchak D, Harrison S, Andron L, Grape R, Hannon R, Clayton W: Neurop-
sychologic Evaluation of HIV Seropositive U.S. Army Soldiers. Fitzsimons
Army Medical Center.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 88 (2) Protocol WU#: 86/116 (3) Status: Ongoing
-
- (4) Title: Endocrine Function in the Acquired Immune Deficiency Syndrome
-
- (5) Start Date: 1986 (6) Est Compl Date: July 1987
-
- (7) Principal Investigator: John Merenich, CPT, MC
Michael T. McDermott, MAJ, MC
Arnold A. Asp, CPT, MC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Endocrine (10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael Bornemann, COL, MC
William J. Georgitis, MAJ, MC
Shannon Harrison, MAJ, MC
David R. Haburchak, COL, MC
-
- (11) Key Words: acquired immunodeficiency syndrome
adrenal glands
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3 pt., 15 controls
d. Total Number of Subjects Enrolled to Date: 40 pt., 20 controls
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None
-
- (15) Study Objective: The objectives of this study are to detect, define, and determine the incidence of abnormalities of the pituitary gland, adrenal gland, thyroid gland and gonads in patients with acquired immune deficiency syndrome and its variants.
- (16) Technical Approach: Patients who are detected as being positive for HTLV III are staged and then endocrine function is studied with a combined pituitary test consisting of the intravenous injection of ACTH, TRH and GnRH with subsequent measurement over the next 3 hours for cortisol, aldosterone, TRH, T₄, T₃, FSH and LH.
- (17) Progress: We completed the data collection phase late 1987 and began data analysis at that time. The adrenal gland data was presented at the 1988 meeting of Endocrine Society. The remainder of the data is currently being analyzed and hope to publish the data within the next few months.
- Presentations:
- (1) Endocrine Society 1988 Annual Meeting, New Orleans, La.
(2) 1988 Fitzsimons Hugh Mahon Competition (2nd place).
- Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/118 (3) Status: Ongoing

(4) Title: Maintenance vs. No Maintenance BCG Immunotherapy of
Superficial Bladder Cancer
SWOG #8507

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
chemotherapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/119 (3) Status: Ongoing

(4) Title: Randomized Comparison of Cisplatin + 5-Fluorouracil vs.
CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced
Squamous Cell Carcinoma of the Head and Neck, Phase III
SWOG #8514

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/120 (3) Status: Ongoing

(4) Title: A Phase II Comparison of CHOP versus m-BACOD versus
ProMaCE-CytaBOM versus MACOP-B in Patients with
Intermediate or High Grade Non-Hodgkin's Lymphoma
SWOG #8516

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 2 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/122 (3) Status: Ongoing

(4) Title: Pulmonary Function Standards at FAMC: Correlation with Anthropomorphic Measurement

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:
Michael E. Perry, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary

(10) Associate Investigators

(11) Key Words:
anthropometry
pulmonary gas exchange

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 19
d. Total Number of Subjects Enrolled to Date: 70
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the spirometry, body plethysmography and diffusion capacity normal standards for Fitzsimons Army Medical Center.

(16) Technical Approach: As pointed out in original protocol, non smoking volunteers undergo spirometry, body plethysmography DLCO, at the PFT lab, chest measurements/height/weight recorded and this data included for regression analysis and assess any correlation.

(17) Progress: Severe staffing shortages prevent work on this protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/123 (3) Status: Ongoing

(4) Title: Phase II Evaluation of Methyl-Glyoxal Bis-Guanylhydrazone
(MGBG) in Patients with Advanced Bladder Cancer
SWOG #8519

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/124 (3) Status: Ongoing

(4) Title: Treatment of Limited Small Cell Lung Cancer with Concurrent
Chemotherapy, Radiotherapy and Intensification with High
Dose Cyclophosphamide
SWOG #8573

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/125 (3) Status: Ongoing

(4) Title: A Randomized Comparative Trial of Lobectomy versus Limited
Resection for Patients with Cancer of the Lung
LCSG #821

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Elder Granger, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/126 (3) Status: Ongoing

(4) Title: A Prospective Randomized Trial to Determine the Benefit
of Surgical Resection of Residual Disease Following
Response of Small Cell Lung Cancer to Combination
Chemotherapy

LCSG #832

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Elder Granger, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/127 (3) Status: Completed

(4) Title: Phase II Pilot Program of Concurrent Chemotherapy and
Radiation Therapy Before Surgery in Patients with
Stage III Non-Small Cell Lung Cancer

LCSG #852

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Daniel Tell, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/128 (3) Status: Ongoing

(4) Title: A Clinical Trial in Patients with Stage II and III
Completely Resected Non-Small Cancer of the Lung
Comparing Chemotherapy vs. No Therapy Following
Surgery
LCSG #853

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Elder Granger, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/129 (3) Status: Ongoing

(4) Title: Evaluation of Ambulatory Recording Oximetry and
Holter Monitoring in Screening for Sleep Apnea

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: (8) Facility: FAMC
Gary L. Jackson, MAJ, MC

(9) Dept/Svc: MED/Pulmonary Dis. (10) Associate Investigators
Jean Foucauld, CPT, MC
Michael Perry, COL, MC

(11) Key Words:
oximetry
sleep apnea syndromes

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To investigate a cost saving method to screen clinically suspected sleep apnea patients with a non-invasive recording pulse oximeter measuring oxyhemoglobin desaturation. No medications will be used. Patients will be seen and evaluated for SAS by the Pulmonary Disease Service.

(16) Technical Approach: Patients are selected on the basis of clinically suspected sleep apnea. Patients are then screened with overnight recording pulse oximetry and studied with holter monitoring simultaneously. Within 24 hours the patients are then studied with a formal sleep study to validate the findings in a positive predictive manner.

(17) Progress: The screening study has been ongoing and is current with respect to data collection and assessment. An abstract was accepted by AM Thoracic Society for publication Apr 88 with the patient number as above, we cannot show a spearman rank differential correlation between screening and formal SAS studies. In the study design, the best evaluation of patients occurs without esophageal balloons in the formal overnight studies.

Presentations: American College of Physicians USA Regional Meeting, San Francisco, CA., October 1987.

Abstract accepted by American Thoracic Society, Las Vegas, Nevada, April, 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/132A (3) Status: Ongoing

(4) Title: The Effect of Theophylline on Calcium and Vitamin D Metabolism in Male Sprague-Dawley Rats

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: (8) Facility: FAMC
Edwin J. Fortenberry, CPT, MC
Michael T. McDermott, MAJ, MC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators
Gerald S. Kidd, COL, MC

(11) Key Words:
theophylline
vitamin D
calcium

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 49 male rats
d. Total Number of Subjects Enrolled to Date: 49 male rats
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of the study are to determine the effect of chronic theophylline administration on calcium and Vitamin D metabolism and bone mineral content in rats.

(16) Technical Approach: Theophylline (n=25) or saline (n=24) are administered by continuous infusion with an Alzet osmotic pump for a period of 4 weeks. After 2 1/2 weeks, measurements are made of 24 hour calcium intake, urine calcium, and fecal calcium excretion and overall calcium balance is calculated. After 4 weeks, the rats are sacrificed and serum calcium PTH, 25 (OH) Vitamin D and 1,25 (OH)₂ vitamin D are measured. The rats are ashed for determination of total body calcium.

(17) Progress: Theophylline treated rats (n=25) had significantly greater urinary calcium excretion and significantly lower 25(OH) Vitamin D levels than did control rats (n=24). They also had slightly lower 1,25 (OH)₂ vitamin D levels and total body calcium per gram of body weight. PTH levels are pending.

Presentations:

(1) McDermott MT, Fortenbery EJ, Duncan WE. Theophylline alters vitamin D and calcium metabolism in rats. 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) McDermott MT, Fortenbery EJ, Duncan WE: Theophylline alters vitamin D and calcium metabolism in rats. J Bone Min Res 3(Suppl. 1): 5115 (188A)

(2) Fortenbery EJ, McDermott MT, Duncan WE: The effect of theophylline on calcium and vitaminD metabolism (Submitted).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

- (1) Date: 30 Sep 88 (2) Protocol WU#: 87/102 (3) Status: Ongoing
- (4) Title: Anti-Histone Antibody Production in Procainamide Associated Drug-Induced Lupus Erythematosus: Association of Serologic Patterns and Lymphocyte Subsets
- (5) Start Date: (6) Est Compl Date: 1989
- (7) Principal Investigator: James D. Singleton, CPT, MC (8) Facility: FAMC
- (9) Dept/Svc: MED/Rheumatology (10) Associate Investigators
Peter A. Andersen, LTC, MC
West, Sterling, LTC, MC
- (11) Key Words:
procainamide
drug-induced lupus
histones
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 14
d. Total Number of Subjects Enrolled to Date: 18
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None
- (15) Study Objective: There are two study objectives: a) to survey the population of patients receiving procainamide to determine baseline data and b) to evaluate a subgroup of patients chosen randomly from patient populations determined by amount of drug administered, serologic status, and the presence of symptomatology.
- (16) Technical Approach: Autoantibodies are one of the hallmarks of SLE yet mechanisms of their production and their pathogenetic import remain unclear. Drug-induced lupus makes feasible the investigation of potential early immunologic abnormalities which would lead to autoantibody production. Demographic, clinical and serologic data will be obtained on patients taking procainamide. Selected patients will, additionally, have T-cell and B-cell lymphocyte studies and be followed serially to discover correlates, if any, in studied parameters.
- (17) Progress: Although only 18 patients have been enrolled in the study and baseline data obtained, approximately 110 individuals receiving procainamide have been identified. Efforts to contact these, obtain informed consent and finally enroll them in the study are ongoing.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/103 (3) Status: Ongoing

(4) Title: Identification of Those at Risk for Osteoporotic Hip Fractures, by a Noninvasive Measurement

(5) Start Date: Jan 87

(6) Est Compl Date: 1989

(7) Principal Investigator:
Jan J. Perloff, CPT, MC
Michael McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology

(10) Associate Investigators

(11) Key Words:
osteoporosis
hip fractures

Gerald S. Kidd, COL, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 70
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate possible risk factors for osteoporosis by comparing hip fracture patients and matched controls for bone density, calcium intake, smoking, medications, mental status, visual acuity, vitamin D levels and exercise history.

(16) Technical Approach: Hip fracture patients, within 5 days of fracture, and normal matched controls will have measurement of bone density at 3 sites in the unaffected hip and in the spine by dual photon absorptiometry and in the non-dominant midradius by single photon absorptiometry. All subjects will have a history and physical examination to include dietary and exercise history. Twenty subjects from each group will have visual acuity and 25-hydroxy vitamin D levels evaluated.

(17) Progress: 20 hip fracture patients and 50 controls have been studied. Hip fracture patients had significantly lower bone density in the hips, marginally lower bone density in the spine, lower calcium intake, more smoking, less exercise, lower vit D levels, worse visual acuity and significantly more organic brain disorders.

Presentations:

(1) McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. Presented: 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) Perloff JJ, McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. J Bone Min Res 3(Suppl. 1):587(73A), 1988, (Abstract).

(2) Perloff JJ, McDermott MT, Perloff KG, Blue PW, Enzenhauer R, Seik E, Chantelois A, Dolbow A, Kidd GS: Risk factors for osteoporotic hip fractures (Submitted for publication).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/104 (3) Status: Ongoing

(4) Title: A Randomized Investigation of High-Dose Versus Standard
Dose Cytosine Abarinoside with Daunorubicin in Patients
with Acute Non-Lymphocytic Leukemia, Phase III
SWOG 8600

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/105 (3) Status: Ongoing

(4) Title: Pre-operative Cimetidine Therapy in Patients Undergoing Parathyroid Exploration: Efficacy and Mechanisms of Action

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
John A. Merenich CPT, MC
Jeffrey R. Clark, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc

(10) Associate Investigators

Michael T. McDermott, MC

(11) Key Words:
hyperparathyroidism
postoperative hypocalcemia

William J. Georgitis, MAJ, MC

Arnold A. Asp, MAJ, MC

Gerald S. Kidd, COL, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 9
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".----Last year one patient developed moderate elevations of liver function tests. She was completely asymptomatic, but her parathyroid surgery was postponed (until her tests returned to normal) and she was dropped from the study. She has subsequently undergone surgery without complications and LFT's remain normal. This year, none of the new patients experienced any complications.

(15) Study Objective: To determine whether or not pre-operative cimetidine therapy can reduce the incidence of post-operative hypocalcemia in patients undergoing parathyroid explorative surgery.

(16) Technical Approach: Patients are given placebo or cimetidine for 10 days prior to their surgery in a double-blind fashion. Calcium and its regulatory hormones are monitored before and after surgery to see if cimetidine favorably alters calcium homeostasis.

(17) Progress: Since the study's implementation, informed consent has been obtained from all but one patient undergoing parathyroid exploration at FAMC. Because the study is double-blinded, no comments concerning the efficacy of cimetidine can be made.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/106 (3) Status: Ongoing

(4) Title: Effect of Concomitant Alcohol and Exercise on High Density Lipoprotein Subfractions and Lipolytic Enzymes in Sedentary, Healthy Men

(5) Start Date: 1987 (6) Est Compl Date: 1988

(7) Principal Investigator: Kerry C. Prewitt, CPT, MC
John A. Merenich, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators
William Georgitis, MAJ, MC
Robert Eckel, MD
Gerald S. Kidd, COL, MC
(11) Key Words:
alcohol
lipoproteins
apolipoproteins
lipase

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine the effects of alcohol alone and in conjunction with exercise on lipid status (and the enzymes that control lipids) in healthy men.

(16) Technical Approach: Participants asked to completely abstain from alcohol or to drink alcohol at social levels while activity levels are manipulated. Lipids and lipoprotein activities are determined before and after these manipulations to assess their effect.

(17) Progress: One of the co-investigators (Dr. Prewitt) has departed Fitzsimons compounding the already difficult recruitment problem. Several participants withdrew from the study citing their unwillingness to abstain from alcohol for 4-8 weeks and/or their inability to maintain the required exercise routine. Fourteen individuals have completed the protocol. We plan on analyzing their specimens and reviewing the data prior to further recruitment attempts.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/107 (3) Status: Completed

(4) Title: Weekly Low Dose CCNU for Extensive Adenocarcinoma of the
Colon and Rectum

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:
Michael Stone, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the efficacy and toxicity of low dose
oral CCNU in colon cancer.

(16) Technical Approach: CCNU 60mg/wk p.o. x 6 wks. If no toxicity in-
crease to 70mg p.o Q wk x 6wks , then 80mg p.o Q wk. Continue theapy as
long as disease is stable and responsive.

(17) Progress: Sufficient patients accrued to complete study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/108 (3) Status: Terminated

(4) Title: Prostaglandin Synthesis Inhibition and Glucose Counter-Regulatory Hormone Secretion in Diabetes Mellitus

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: Robert J. Sjoberg, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators
John Merenich, CPT, MC
Gerald S. Kidd, COL, MC
T.P. O'Barr, DAC

(11) Key Words:
prostaglandin synthesis
glucose counter regulation
diabetes mellitus
hypoglycemia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if and how well choline magnesium trisalicylate reverses the glucose counter-regulatory hormone defect and delayed hypoglycemia recovery associated with Type I diabetes mellitus.

(16) Technical Approach: To study 25 patients with Type I diabetes mellitus who are not excluded from the study (see exclusion criteria in protocol). The patients will be given an insulin infusion to cause slow onset hypoglycemia. Glucagon, epinephrine, glucose nadir, and the rate of glucose recovery will be determined with and without prior treatment with choline magnesium trisalicylate.

(17) Progress: Because of the complexity of this protocol (especially the time commitment) from the subject participation point of view, it has been impossible to recruit participants. We see no other logistically easier way to answer the scientific question posed by this protocol and therefore wish to terminate this study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/109 (3) Status: Completed

(4) Title: The Efficacy of Conjugated Estrogens in Reducing Blood Loss During and After Cardiac Surgery; Decreased Endothelial Prostacyclin Production as a Possible Mechanism

(5) Start Date: June 1987 (6) Est Compl Date: June 1988

(7) Principal Investigator: James A. Hasbargen, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Internal Med. (10) Associate Investigators

R. Hull, MD

(11) Key Words:

S. Fall, MD

estrogen

T.P. O'Barr, Ph.D.

bypass loagulopathy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: a. Efficacy of conjugated estrogens in reducing blood loss of bypass surgery and, b. Explore effects on prostacyclin production as a possible mechanism.

(16) Technical Approach: Patient receives I.V. conjugated estrogens 3 days prior to surgery. Venous PGF1 levels before and after infusion period. Vein sample also assayed for prostacyclin production. Blood loss of surgery and post-op period recorded for analyses between placebo and experimental groups.

(17) Progress: Enrolled proposed patients. No adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/110 (3) Status: Ongoing

(4) Title: The Role of Excess Prostaglandin Production in Causing
The Abnormal Hemodynamic Status of Adrenalectomized Rats

(5) Start Date: 1987 (6) Est Compl Date: 1989

(7) Principal Investigator: Robert J. Sjoberg, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators
John Merenich CPT, MC
Gerald S. Kidd, COL, MC
T.P. O'Barr, DAC
(11) Key Words:
prostaglandins
adrenal insufficiency

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To clarify the role of altered renal and arterial prostaglandin production in mediating the hemodynamic alterations associated with adrenal insufficiency.

(16) Technical Approach: The approach used involved investigations of a) comparison of the physiologic response of adrenalectomized rats to prostaglandin synthesis inhibitors and to glucocorticoid replacement and b) the ex vivo elaboration of prostaglandins by renal and arterial tissue taken from adrenalectomized rats.

(17) Progress: This study as outlined in the original protocol has been completed. An addendum to this protocol was presented to the Laboratory Animal Care & Use Committee on 24 Feb 1988. Data from the original protocol suggests that renal prostaglandins are increased post-adrenalectomy, that this is due to intravascular volume depletion, and that this does not contribute to natriuresis and hyperreninemia. A known physiologic dose of a glucocorticoid did not, however, correct these abnormalities, giving into question the animal model used. The addendum presented addresses this issue further. It is anticipated that these further studies will be completed within the next year.

Presentations: Sjoberg R, Merenich J, O'Barr, Kidd G: Renal and arterial prostaglandin production in insufficiency. (Abstract) Presented: 70th Annual Meeting of the Endocrine Society, New Orleans, La, 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/111 (3) Status: Ongoing

(4) Title: A Prospective Double Blind Study of Retrovir in Early HIV Infection

(5) Start Date: (6) Est Compl Date: 1991

(7) Principal Investigator: Shannon Harrison, LTC, MC (8) Facility: FAMC Denver Health & Hospitals

(9) Dept/Svc: MED/Inf. Dis. (10) Associate Investigators

(11) Key Words: R.N. Hannon, PA-C
Leo Andron, LTC, MS
Robert H. Gates, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report. (Feced HSC/HIV monies & P6 MED R&D Grant)

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 59FAMC/100DH&H
d. Total Number of Subjects Enrolled to Date: 59 & 100
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To look for efficacy and toxicity in terms of difference in natural history of Walter Reed Stage II through early V, HIV infected individuals given zidovudine at 200mg every 6 hours vs placebo.

(16) Technical Approach: See protocol.

(17) Progress: Protocol is actively inputting patients and enrollment is expected to close 1 January 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 88 (2) Protocol WU#: 87/112 (3) Status: Ongoing
-
- (4) Title: (RTOG-85-01) Prospective Trial for Localized Cancer of The
Esophagus: Comparing Radiation as a Single Modality to the
Combination of Radiation Therapy and Chemotherapy, Phase
III Intergroup
SWOG-8598
-
- (5) Start Date: (6) Est Compl Date: Indefinite
-
- (7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
drug therapy 11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".
-
- (15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.
- (16) Technical Approach: See Protocol
- (17) Progress: In progress.
- Publications and Presentations: None

FAMC A.T.R. (PCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/113 (3) Status: Ongoing

(4) Title: A Phase II Randomized Trial of Combination Therapy for Multiple Myeloma: Comparison of (1) VMCP/VBAP to VAD or VMCPP/VBAPP for Induction, (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha -2b Interferon + Dexamethasone for Incomplete or Nonresponders

SWOG 8624

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words: drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Protocol ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/114 (3) Status: Ongoing

(4) Title: Patient Evaluation of Physicians' Humanistic Qualities

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gen. Med Svc. (10) Associate Investigators
Cathy L. Ow, CPT, MC

(11) Key Words:
humanistic qualities
medical residents

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) to determine what behaviors are considered by patients to be important markers of humanistic qualities in their physicians; b) to develop and test a questionnaire for a patient to rate the humanistic qualities of their own physician, and (c) to determine whether feedback, based on their own patients' ratings, can result in a change in physicians' humanistic behaviors.

(16) Technical Approach: The study consists of three phases: (a) open-ended interviews with patients to elicit important physicians' humanistic behaviors; (b) development and testing of a questionnaire from the responses generated in Phase a, and (c) we will give back feedback to physicians, based on their own patients' evaluation of their humanistic behaviors, using the questionnaire developed, and measure whether there is any change on a repeat questionnaire, post-feedback.

(17) Progress: Protocol is ongoing. Data is being collected for phase (b).

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/113 (3) Status: Ongoing

(4) Title: A Phase II Randomized Trial of Combination Therapy for Multiple Myeloma: Comparison of (1) VMCP/VBAP to VAD or VMCP/VBAPP for Induction, (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha -2b Interferon + Dexamethasone for Incomplete or Nonresponders

SWOG 8624

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Daniel Tell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol.

(17) Progress: Protocol ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

- (1) Date: 30 Sep 88 (2) Protocol WU#: 87/114 (3) Status: Ongoing
- (4) Title: Patient Evaluation of Physicians' Humanistic Qualities
- (5) Start Date: (6) Est Compl Date:
- (7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC
- (9) Dept/Svc: MED/Gen. Med Svc. (10) Associate Investigators
Cathy L. Ow, CPT, MC
- (11) Key Words:
humanistic qualities
medical residents
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: a) to determine what behaviors are considered by patients to be important markers of humanistic qualities in their physicians; b) to develop and test a questionnaire for a patient to rate the humanistic qualities of their own physician, and (c) to determine whether feedback, based on their own patients' ratings, can result in a change in physicians' humanistic behaviors.
- (16) Technical Approach: The study consists of three phases: (a) open-ended interviews with patients to elicit important physicians' humanistic behaviors; (b) development and testing of a questionnaire from the responses generated in Phase a, and (c) we will give back feedback to physicians, based on their own patients' evaluation of their humanistic behaviors, using the questionnaire developed, and measure whether there is any change on a repeat questionnaire, post-feedback.
- (17) Progress: Protocol is ongoing. Data is being collected for phase (b).

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/115 (3) Status: Ongoing

(4) Title: Double Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: James D. Bales, Jr., COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf Dis Svc. (10) Associate Investigators
Shannon M. Harrison, LTC, MC
Robert H. Gates, MAJ, MC

(11) Key Words:
gram negative shock
gram negative sepsis
monoclonal antibody
HA-1A monoclonal antibody

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Objective: To determine the efficacy of HA-1A monoclonal antibody in reducing the mortality and/or direct morbidity of gram-negative sepsis as compared to a placebo treated control group. To determine the impact that HA-1A has on patient benefit. To determine the impact that HA-1A has on laboratory parameters/clinical signs associated with sepsis. To determine the safety and potential for immunogenicity of HA-1A monoclonal antibody administration in patients presenting with clinical syndrome of gram-negative sepsis.

(16) Technical Approach: Patients with the clinical diagnosis of septic shock or sepsis suspected of being secondary to gram-negative organisms will be treated with one dose of either placebo or HA-1A monoclonal antibody. A comparison of morbidity and mortality between the placebo and HA-1A group will be made to determine efficacy and safety of the drug.

(17) Progress: None. The drug has been unavailable. The drug is due to be available mid-September 1988. No progress this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/116 (3) Status: Ongoing

(4) Title: Effect of Iodine Containing Water Purification Tablets
on Thyroid Function in Man

(5) Start Date: Aug 87

(6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, MAJ, MC
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators
John R. Barrett, LTC, MC
William J. Georgitis, LTC, MC
Robert J. Sjoberg, MAJ, MC
John A. Merenich, CPT, MC
Kenneth Simcic, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study are to investigate the effects of iodine containing water purification tablets on thyroid function and job performance in soldiers in a field environment.

(16) Technical Approach: See Protocol

(17) Progress: This is a new study just approved in August, 1987. No one volunteered for the study during the Spring 1988. Field training exercises and volunteers are now being sought for the Fall 1988 and/or Spring 1989 FTX's.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/117 (3) Status: Ongoing

(4) Title: Analysis of von Willebrand Factor Multimers Before
and After Cardiopulmonary Bypass

(5) Start Date: 1987 (6) Est Compl Date:

(7) Principal Investigator: Scott Brantley, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hem/Oncol (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the effect of the cardiopulmonary
bypass machine on the multimeric structure of von Willebrand's factor
and to provide clinical research experience for FAMC residents and
staff.

(16) Technical Approach: See Protocol

(17) Progress: No results are currently available. No risks have been
identified. Benefit lies in revealing the etiology of hemostatic abnor-
malities associated with bypass surgery. There has been no new pub-
lished data of the kind proposed. Problems encountered: successful
performance of the von Willebrand multimer electrophoresis procedures
and this problem is slowly being rectified. Enrollment of adequate con-
trol patients due to decreased surgical load.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/100 (3) Status: Completed

(4) Title: LCSG 861 Pilot Study to Evaluate the Efficacy of
Intrapleural Chemotherapy in the Mangement of Malignant
Pleural Effusions

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Daniel T. Tell, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hemo/Oncol

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: See Protocol

(16) Technical Approach: See Protocol

(17) Progress: Completed

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/101 (3) Status: Ongoing
(4) Title: LCSG 871 Centralized Non-Small Cell Lung Cancer Specimen
Repository and DNA/RNA Bank

(5) Start Date: (6) Est Compl Date:
(7) Principal Investigator: (8) Facility: FAMC
Daniel T. Tell, MAJ, MC

(9) Dept/Svc: MED/Hem/Oncol (10) Associate Investigators
(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: See Protocol

(16) Technical Approach: See Protocol

(17) Progress: Protocol is ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/102 (3) Status: Ongoing

(4) Title: Effect of Chronic Coumadin Therapy on Cortical and Trabecular Bone Density in Man

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Wheaton Williams, CPT, MC
Jan J. Perloff, CPT, MC
Michael McDermott, MAJ, MC

(9) Dept/Svc: MED/Endocrine Svc. (10) Associate Investigators
Gerald S. Kidd, COL, MC
(11) Key Words: Peter Blue, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to investigate the bone density of cortical and trabecular bone in patients on chronic coumadin therapy and in age-matched controls.

(16) Technical Approach:

(17) Progress: Protocol just approved August 1988.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/103 (3) Status: Ongoing

(4) Title: Clinical Efficacy of Phenindamine as Determined
by Skin Test Suppression

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Richard W. Weber, COL, MC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators
Grant C. Olson, CPT, MC

(11) Key Words:
antihistamine
phenindamine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To examine the null hypotheses that there is no
difference in skin test suppression and side effects produced by phenin-
damine 25mg qid, chlorpheniramine 8mg tid, and placebo in 2 week trials
in normal subjects.

(16) Technical Approach: Twenty subjects will take part in a placebo
controlled crossover study of the skin test suppression produced by
phenindamine, chlorpheniramine, and placebo. Results will be used to
evaluate the efficacy, as determined by skin test suppression, of
phenindamine compared to chlorpheniramine and placebo.

(17) Progress: Assigned to fellow for initiation. Consent form up-
dated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 88 (2) Protocol WU#: 88/104 (3) Status: Ongoing
-
- (4) Title: A Descriptive Study of Pastoral Care Interventions Designed to Assist HIV+/AIDS Patients in Achieving Their Maximum Quality of Life
-
- (5) Start Date: (6) Est Compl Date: 1990
-
- (7) Principal Investigator: F. William Miles, LTC, USAR (Chaplain) (8) Facility: FAMC
-
- (9) Dept/Svc: Minis. & Past. Care (10) Associate Investigators
Shannon M. Harrison, LTC, MC
Robert L. Campbell (CH), COL
-
- (11) Key Words: psycho-social-spiritual
cognitive, moral & faith development
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: Tst/178/Intr/76
d. Total Number of Subjects Enrolled to Date: Tst/178/Intr76
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NA
-
- (15) Study Objective: (a) To observe and document the continuity of pastoral care with a traumatically stressed patient population (FAMC and beyond). (b) To conduct a longitudinal descriptive study that shows process from the point of view of patient, family member, supervisor and pastoral care giver. (c) To encourage personal processing of issues that impact on a sense of well being, decision making, psycho-social-spiritual growth through the use of an intentional and prescribed series of pastoral interventions. To provide the patient personal gain from telling his/her own "story." (d) To look at life histories, values, moral/faith development, personality types as they inform the pastoral care giver for ministry.
-
- (16) Technical Approach: We are developing a pastoral data base of information relative to providing pastoral care to HIV+/AIDS patients. This is accomplished through regular personality inventories and interviews every six months during the HIV staging process, as well as follow-up questionnaires and support visits/calls to determine continuity of pastoral care and individuals functioning at unit/home.

(17) Progress: The protocol is still in the data gathering phase. During the past year, the following testing was completed in the HIV Pastoral Research Project (began testing o/a 1 Oct 87):

- a. Patients tested - 178 [(B=81,W=81,H=18) (WOMEN=27,P=15) (HIV-=31)]
- b. Second testings - 44
- c. Third testings - 3
- d. Values inven. - 156 (+17 HIV-)
- e. D.I.T. - 141 (+14 HIV-)
- f. MBTI - 175
- g. TJTA - 220 (150+, 23-)
- h. Fowler Interviews 76
- i. 2nd Interviews 6

There is an observation that the Taylor Johnson Temperament Analysis seems to indicate in the upper/lower 20 percentiles that an individual is showing signs of stress, which are confirmed by other psychological testing and psychiatric interviews. None of the prisoners tested prefer "Intuitive" on the Myers-Briggs Type indicator.

Publications:

(1) For the General Convention of the Episcopal Church, Detroit, Michigan, July 1988, Short article describing the research projects being conducted in Infectious Disease Service/DMPC at FAMC.

Presentations:

(1) Psycho-social-spiritual Aspects of HIV+Patients: Presented: Ft. Leavenworth, Kansas, September 1987.

(2) AIDS for professionals, The Next Step. 2 presentations: "Guilt, Shame, and Grief" and "A Wellness/wholeness Approach for the HIV+ Patient." New York City, 15 April 1988.

(3) Episcopal Diocese of Colorado Workshop: AIDS, The Church's Response. w/Mr. Hannon and Dr. Harrison. Presented: Denver, Colorado, 6-7 February 1988.

(4) HIV/AIDS Briefing - Psycho-social-spiritual Aspects. Physical Therapy Students. Presented: University of Colorado Medical Center, Denver, CO, April 1988.

(5) HIV/AIDS Briefing/A Psycho-Social-Spiritual Model of Wellness in the HIV+ Patient. Presented: MEDDAC, Ft. Hood, Texas, May 1988.

(6) HIV/AIDS Update-A Psycho-Social-Spiritual Model of Wellness in the HIV+ Patient. Presented: Chaplain Training Conference, Health Services Command, San Antonio, TX, May 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/105 (3) Status: Ongoing

(4) Title: Detection of Unsuspected Disease by the Complete Physical Exam

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: (8) Facility: FAMC
Homer J. LeMar, Jr., MAJ, MC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators
Michael J. Weaver, COL, MC

(11) Key Words:
physical exam
screening

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine which specific areas of routine screening physical examination of patients at the time of hospital admission detects unsuspected disease, and leads to significant changes in medical management.

(16) Technical Approach: The study will consist of a chart review of in-patient records of patients who were admitted to, and discharged alive from the general medicine wards, after a hospital stay of more than three days. Only charts with a complete admission history and physical examination on the chart will be reviewed. We will begin with 100 charts, and will review more if needed to find sufficient "unexpected" findings. One investigator will review the admission history, including the presenting or chief complaint, the history of the present illness, the past medical history, and the review of systems, without knowledge of the physical examination. All positive findings in the history will be listed, and for each historical finding, we will determine what areas of the physical examination would be pertinent, or in which abnormal findings should be sought and might be expected. These areas of the physical examination will be considered "diagnostic" rather than "screening." The other investigator will review the physical examination, without knowledge of the history, listing all abnormal physical findings, by area. We will then compare the results of the review of

the history with the review of the physical examination to determine the yield of the "screening" examination, that is, which physical findings, if any, would not have been expected from the history, or would not have been discovered on examination of only historically relevant or indicated areas. We will then review each chart in detail to determine what tests were done to evaluate the unexpected physical findings, and what changes in management or therapy occurred as a result of these unexpected findings. Based on this, we will determine the utility, or contribution to patient care, of the "screening" physical examination.

(17) Progress: To date we have reviewed over 60 charts. Our goal is to review 100 charts.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/106 (3) Status: Ongoing

(4) Title: Use of Nifedipine Gastrointestinal Therapeutic System in the Treatment of Hypertension

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: J. Hasbargen, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology Svc. (10) Associate Investigators

(11) Key Words: nifedipine
hypertension V. Bray
J. Lockard

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the efficacy of the gastrointestinal therapeutic system utilizing nifedipine in the control of hypertension.

(16) Technical Approach: Study with baseline, titration, and efficacy phases study. Blood studies and baseline and after 12 week efficacy period.

(17) Progress: Three patients enrolled in week 2-3 of study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/108 (3) Status: Ongoing

(4) Title: The Effect of Thyroid Hormone Administration in Acute Renal Failure

(5) Start Date: (6) Est Compl Date: 1991

(7) Principal Investigator: J. Lockard, MD (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology Svc. (10) Associate Investigators M. Porogy

(11) Key Words:
acute renal failure
thyroxine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Efficacy of thyroxine in amelioration of acute renal failure.

(16) Technical Approach: Thyroxine vs placebo to patients with ARF. Serum creatinine, urine output followed. T₄, TSH will be assayed at WRAMC.

(17) Progress: This is a collaborative study. One patient enrolled and no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/109 (3) Status: Ongoing

(4) Title: Methotrexate in the Treatment of Steroid Dependent
Asthmatics

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: (8) Facility: FAMC
Richard W. Weber, COL, MC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators
Thurman R. Vaughan, MAJ, MC
(11) Key Words: Philip D. Dyer, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effectiveness of weekly
methotrexate in reducing the steroid requirements of steroid dependent
asthmatics. The purpose is to demonstrate a statically significant
reduction in the steroid dose over the placebo control, without involve-
ment of the other parameters.

(16) Technical Approach: Double blind crossover design with methotrexate
and placebo following pulmonary function tests, symptom scores with at-
tempt to taper corticosteroids.

(17) Progress: 7 patients enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/110A (3) Status: Ongoing

(4) Title: Biological Investigation of Cutaneous Lupus Employing
Athymic Mice as Skin Heterotransplant Recipients

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Ramsey Mellette, COL, MC
Lela Lee, M.D.

(8) Facility: FAMC
UCHSC

(9) Dept/Svc: MED/Dermatology Svc. (10) Associate Investigators

Larry Urry, MAJ, MC

(11) Key Words:

Don Mercill, DAC

Silviya Coulter, UCHSC

James Fitzpatrick, LTC, MC

William Weston, MD, UCHSC

Charles F. Ferris, CPT, MS

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in vivo model demonstrating cutaneous lupus as manifested in humans and to use such model to sequentially study the biological causes of the diseases.

(16) Technical Approach: See Protocol.

(17) Progress: Protocol does not come up for continuing review until 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/111 (3) Status: Ongoing

(4) Title: The Use of Fibrin Monomer and D-Dimer in the Evaluation of Patients with Chest Pain

(5) Start Date: April 1988 (6) Est Compl Date: April 1989

(7) Principal Investigator: Mark E. Dorosy, CPT, MC
Robert W. Hull, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Internal Med Svc (10) Associate Investigators

Leo W. Jordan, MAJ, MC
Steven H. Atchley, MAJ, MCC
(11) Key Words:
fibrin monomer
D-dimer
unstable coronary artery disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the diagnostic usefulness of fibrin monomer and D-dimer in patients presenting with chest pain requiring evaluation for unstable coronary disease. To determine the prognostic value of these levels in patients with unstable angina and acute myocardial infarction.

(16) Technical Approach: Patients admitted to the CCU for evaluation of chest pain are divided into two groups - those with unstable coronary d3 (MI, unstable angina), and those determined to have noncardiac chest pain based on initial history and physical, EKG, serial CK determinations and additional workup (TMST, cardiac cath, etc.). Blood is drawn at the time of admission for determination of fibrin monomer and D-dimer levels.

(7) Progress: To date, 21 patients have been enrolled. Further enrollment has been postponed pending review of results from the mital series. We are currently in the process of running the fibrin monomer and D-dimer assays.

Publications and Presentations: Information is to be presented in abstract form at the 1988 Army ACP metings, Cardiology section by Dr. Hull.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/112 (3) Status: Ongoing

(4) Title: Long Term 5-Fluorouracil Infusion for Recurrent Head
and Neck Cancer

(5) Start Date: 1988

(6) Est Compl Date:

(7) Principal Investigator:
Patrick W. Cobb, CPT, MC
Daniel T. Tell, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hem/Oncol Svc

(10) Associate Investigators
Frank Ward, MAJ, MC
Denis Lanier, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The study is designed to assess the effectiveness
of a continuous infusion of 5-FU on patients with recurrent head and
neck cancer. Tumor response, toxicity and survival will be monitored.

(16) Technical Approach: See Protocol.

(7) Progress: Protocol will not come up for continuing review until June
1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/113 (3) Status: Ongoing

(4) Title: Methotrexate versus D-Penicillamine in Rheumatoid Arthritis: A Randomized Comparative Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: James D. Singleton, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology Svc (10) Associate Investigators
Sterling G. West, LTC, MC
David M. Nordstrom, MAJ, MC

(11) Key Words:
methotrexate
D-penicillamine
rheumatoid arthritis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 12
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare clinical efficacy, toxicity and radiographic progression of joint disease in patients receiving methotrexate or D-penicillamine.

(16) Technical Approach: Patients with rheumatoid arthritis will be randomly assigned to receive either methotrexate or D-penicillamine. Clinical assessment will be performed every 3 months and radiographic assessment every year.

(7) Progress: A total of 12 pts have now been enrolled in the study and are undergoing serial assessments.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/114 (3) Status: Ongoing

(4) Title: Crossover Comparison of Maximum Dose Glyburide and Glipizide

(5) Start Date: 1988 (6) Est Compl Date: 1989

(7) Principal Investigator: Kenneth J. Simcic, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators
Michael T. McDermott, LTC, MC
William J. Georgitis, LTC, MC
Gerald Kidd, COL, MC
Nancy Pfander, MAJ, MC
(11) Key Words:
diabetes (type II)
oral hypoglycemic agents
glyburide
glipizide

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 28
d. Total Number of Subjects Enrolled to Date: 28
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To examine whether or not significant improvements in fasting serum glucose, hemoglobin A1C1 and blood lipids occur when type II diabetic patients' failing therapy with either glyburide or glipizide are switched to the alternate second generation sulfonylurea agent.

(16) Technical Approach: This trial is a single-center prospective, open crossover study in which type II diabetic patients are switched from a maximum dose of one second-generation sulfonylurea agent (glyburide or glipizide) to the maximum dose of the other agent.

(7) Progress: Thus far, 28 patients have been enrolled and no further patient enrollment is planned. One patient has been withdrawn because of a recurrence of breast cancer. All but 3 patients are at or beyond phase II (crossover phase) of the study. It is expected that most patients will have completed the study by Dec. 88. A few will require continuation until approx. 1 March 88. No complications or adverse reactions have occurred.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/115 (3) Status: Ongoing

(4) Title: The Impact of an Ambulatory Care Rotation on Interns
Psychosocial Attitudes

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael J. Weaver, COL, MC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.

(16) Technical Approach:

(17) Progress: No progress as this is a new study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/116A (3) Status: Ongoing

(4) Title: Mouse Anti-Chenopod/Amaranth Pollen Monoclonal
Antibody Production

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Richard W. Weber, COL, MC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators
Thurman R. Vaughan, MAJ, MC
(11) Key Words: Lawrence V. Larsen, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To develop mouse monoclonal antibodies to
chenopod-amaranth pollen antigens. The purpose is to use these an-
tibodies to study the crossreactivity of chenopod-amaranth pollen an-
tigens. The importance of the latter is the eventual improvement of al-
lergen extracts for diagnostic and therapeutic utilizations.

(16) Technical Approach: Stage I: Characterization of allergen extracts
by PAGE and Western Blot. Stage II: Monoclonal antibody production and
characterization by injecting mice with allergen extract, screen for an-
tibody with ELISA, and develop hybridomas.

(17) Progress: Stage I shows good characterization of extract by PAGE.
Mice presently being injected and boosted.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/117 (3) Status: Ongoing

(4) Title: A Comparison of Amitriptyline vs. Trazodone vs. Placebo
as Adjuvants to Opiate Analgesics in the Management of
Pain in Cancer Patients

(5) Start Date: 1988

(6) Est Compl Date:

(7) Principal Investigator:
Daniel T. Tell, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hemo/Oncol Svc

(10) Associate Investigators
Rose A. Gates, MAJ, ANC

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a. To compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases; b. Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate; c. Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics in the treatment of pain associated with malignant disease.

(16) Technical Approach:

(7) Progress: No progress as this is a newly approved study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/118 (3) Status: Ongoing

(4) Title: CAP Study 12-21-87 - Use of Nifedipine (Gastrointestinal
Therapeutic System) in the Treatment of Angina Pectoris

(5) Start Date: 1988 (6) Est Compl Date: 1989

(7) Principal Investigator: (8) Facility: FAMC
Richard C. Davis, Jr., COL, MC

(9) Dept/Svc: MED/Cardiology Svc (10) Associate Investigators
John M. VanDeren, III, CPT, MC

(11) Key Words:
nifedipine GITS
angina pectoris
silent ischemia

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost: *
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None

(15) Study Objective: To establish the efficacy of Nifedipine GITS as
monotherapy or combined therapy with beta blockers in angina pectoris.
Secondly, to try to clarify some of the issues regarding mechanism of
action of a new delivery system, Nifedipine GITS compared to other an-
tianginal therapies.

(16) Technical Approach: Qualified patients will be placed on Nifedipine
GITS placebo in a single blind fashion after all other antianginal
therapy except beta blockers are discontinued. They will then undergo
Holter monitoring. Those with objective evidence of ischemia will be
placed on Nifedipine GITS and dose titrated over 7-12 weeks to maximum
efficacy with Holter monitoring performed at the completion of the ef-
ficacy phase. A single blind placebo control period will then be
repeated with Holter monitoring at the completion.

(7) Progress: To date, the ST segment Holter monitoring equipment has
been installed and its proper function is being validated. The first
study patients should be enrolled in the next 1-2 weeks.

Publications and Presentations: None

DEPARTMENT OF SURGERY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

Floyd M. Cornell, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

Norman T. Byers, COL, MC

(11) Key Words:

intraocular lens

Allan W. Berg, COL, MC

W. Manning Maulding, MAJ, MC

E.A. Cohn, CPT, MC

Michael W. Coatney, MAJ, MC

Robert W. Enzenauer, MAJ, MC

David R. Pernelli, CPT, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

3M, ALCON, IOLAB (PRECISION-COSMET), COBURN

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: Results have been excellent with over 1,000 subjects enrolled. No adverse reactions encountered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Luis Colon, MAJ, MC (8) Facility: FAMC
General Leonard Wood Army
Community Hospital

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 42
d. Total Number of Subjects Enrolled to Date: 62
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To establish the safety and effectiveness of
intraocular lens implantation of the cataract patient. (See original
protocol)

(16) Technical Approach: Extracapsular cataract extraction with posterior
chamber IOL.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Jeffrey L. Bezier, CPT, MC

(8) Facility: FAMC
Reynolds Army Hospital
Ophthalmology, Box 21
4700 Hartell Blvd.
Ft. Sill, OK 73503-6300

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 35
d. Total Number of Subjects Enrolled to Date: 85
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: Visual acuity testing and keratometry. Contraindications to surgery include: Proliferative diabetic retinopathy, rubeosis irides.

Implanting CILCO lenses now, but also authorized to implant Precision Co. Cosmet, 3M, Alcon, and IOLAB.

(17) Progress: Cataract surgery with the intraocular lens implantation has been satisfactory with no unusual post operative complications to date. There has been one retina detachment occurring 5 weeks post secondary intraocular lens implant. Approximately 75 posterior chamber and 10 anterior chamber lenses have been implanted by Dr. Bezier at RACH between August 86 and August 88.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Ricardo J. Ramirez, MC

(8) Facility: FAMC
Irwin Army Community Hospital
Ft. Riley, Kansas 66442

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 326

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and compare those results with those who undergo cataract surgery without an implant. To determine the occurrence and time of postoperative ocular complications and adverse reactions for intraocular lens implant; to identify subgroups within the implant group that are risk of a particular complication.

(16) Technical Approach: After completing his residency, didactic courses, laboratory practice and assistance with an experienced surgeon, a surgeon who can perform a successful cataract surgery is then allowed to perform intraocular lens surgery. Postoperative examination includes: refraction, pachymetry, keratometry and a complete anterior and posterior segment examination. Contraindications to surgery with intraocular implants include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, any history of anterior or posterior uveitis. History of glaucoma would preclude the use of an anterior chamber implant.

(17) Progress: We have now implanted 326 intraocular implants. Our study includes tabulation of operative complications, visual acuities, endothelial cell loss, changes in corneal astigmatism and residual refractive error. As a result of similar studies many intraocular lens have been removed from the market because of particular complications or as a result of the development of better lens.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/201E (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Charles E. Aronson, COL MC

(8) Facility: FAMC
Evans Army Community Hospital
Ophthalmology,
Ft. Carson, CO

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:
intraocular lens

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 88

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Participation in IOL implantation.

(16) Technical Approach: See protocol.

(17) Progress: In the last Fiscal Year the Ophthalmology Service has implanted exclusively either the Coburn #72 UV Posterior Chamber or the Coburn #121 UV lens. We have implanted 85 of the 72 UV lens and 3 of the 121 UV lens. The 72 UV lens is our primary lens of choice in patients undergoing extracapsular cataract extractions and we find it to be an excellent lens with good centering ability over a prolonged period. We have not had to reposition or remove any lens because of subluxation or dislocation. There is no evidence of chronic uveitis or late onset hyphema or glaucoma with these lenses. The 121 UV lens (Anterior Chamber) is used as the lens to be placed in patients undergoing secondary lens implantation following a previous cataract extraction or in those patients with vitreous loss due to posterior capsular rupture at the time of the initial extracapsular cataract extract. We have had two complications using this lens, both in the same patient. This is the onset of cystoid macular edema in both eyes of one patient following secondary anterior chamber IOL implants. This patient has had previous intracapsular cataract extractions and there was evidence of vitreous strands through the pupils of both eyes post-op suggesting that vitreous tractions is most likely the etiology of the C.M.E. and not the fault of the anterior chamber 121 UV IOL.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/20X-001 (3) Status: Ongoing

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
James C. Johns, Jr.
MAJ, MC

(9) Dept/Svc: SUR/Orthopedic (10) Associate Investigators

(11) Key Words:
microvascular education
and training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for orthopedic staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: Ongoing education in microvascular surgery continues.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/20X-002 (3) Status: Ongoing

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and the Rat

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Kenneth F. Casey, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Neurosurgery (10) Associate Investigators

(11) Key Words:
microvascular education
and training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: This protocol is continuing with excellent results. Animal use over the last several months has been curtailed with deference to the current budgetary difficulties. We anticipate, with continued approval of the protocol, resumption of activities with new fiscal year. This will coincide with the arrival of the first University of Colorado Health Sciences Center resident, and will not hamper the ongoing training of FAMC residents.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/20X-003 (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
John D. Rich, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Plastic Surgery (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Five plastic surgery fellows have been trained in microvascular surgery. This has resulted in several revascularizations of compromised extremities in human patients. We feel that the rat has proven to be a suitable animal model. It is less expensive to use rats than to use rabbits, therefore, we are modifying to protocol to include a rat model only. The only problem we note has been the inability to perform a second procedure on an animal in order to check a previous anastomosis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 84/20X-001 (3) Status: Ongoing

(4) Title: Microvascular Arterial and Venous Anastomosis in
Laboratory Rats

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

Michael J. Riafe
LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology

(10) Associate Investigators

Daniel W. Horne, LTC, MC

(11) Key Words:

Craig Donatucci, MAJ, MC

Clyde R. Roy, II, MAJ, MC

Deogracia Quinones, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To develop and maintain microvascular skills.

(16) Technical Approach: Microsurgical exercises of increasing complexity
will be performed under anesthesia.

(17) Progress: Due to resident personnel shortages in 1987, the protocol
was generally inactive over the past year. We do plan to restart training
in October, 1988. The protocol has been valuable in the past.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/200 (3) Status: Completed

(4) Title: Differential Fixation of Centrifuged and Non-Centrifuged
Acrylic Bone Cement Specimens

(5) Start Date: 1985 (6) Est Compl Date: 1988

(7) Principal Investigator: Joseph N. Wilson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
Joe K. Ozaki, COL, MC

(11) Key Words:
bone cements
acrylic resins

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: We propose to study volumetric change in acrylic cement as it is used in surgery with and without centrifugation; strength of bonding of acrylic cement to bone and to the prosthesis by "pull out" strength testing comparing cements with and without centrifugation and the variability of the shrinkage in the different type of acrylic cement available for orthopedic surgical use.

(16) Technical Approach: Acrylic bone cement will be mixed and changes recorded by direct and indirect (fluid displacement) methods. Model systems of initial/cement/bone will be tested to determine bonding strength of interface using a tensiometer.

(17) Progress: First stage of experiments are complete and have been presented at national and international meetings, fixation experiments are ongoing at this time. Study is completed.

Presentations:

Wilson, J.N.: Volume Changes During Polymerization. Presented: Barnard Seminar, Denver, CO March 1985.

Wilson JN: Volume Changes During Polymerization. Presented: SOMOS' 1986, Society of Military Orthopedic Surgeons, Colorado Springs, CO.

Wilson JN: Volume Changes During Polymerization. Presented: International Symposium on Orthopedics, Mexico, September 1987.

Publications: In preparation.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/202 (3) Status: Completed

(4) Title: NSABP Protocol C-02 - A Clinical Trial Evaluating the
Postoperative Portal Vein Infusion of 5-Fluorouracil
and Sodium Heparin in Patients with Resectable
Adenocarcinoma of the Colon

(5) Start Date: 1985 (6) Est Compl Date: 1988

(7) Principal Investigator: William H. Marx, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc. (10) Associate Investigators
Jerry E. Sims, MD
Jeffrey R. Clark, MC

(11) Key Words:
colonic neoplasms
heparin
fluorouracil

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To determine the efficacy of perioperative portal
vein infusion as an adjuvant therapy in patients with Duke's A, B. and C
adenocarcinoma of the colon as compared to standard therapy which is sur-
gery alone. The study is designed to determine whether there will be
prolongation of the disease-free interval and increasing survivorship in
patients undergoing curative resection of colonic adenocarcinoma and
treated in this manner.

(16) Technical Approach: Patients will be assigned by random selection to
one of the following groups: a) surgery alone; b) surgery plus additional
continuous portal vein infusion with 5-FU 600 mg/M² and 5000 units sodium
heparin per day, given for a total of 7 consecutive days. Portal vein
catheters will be inserted intraoperatively after the colonic anastomosis
has been completed. All portal vein infusions will be started within 6
hours of the operative procedure.

(17) Progress: Protocol closed in July 1988.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/200 (3) Status: Ongoing

(4) Title: Treatment of Urinary Tract Trauma in the Porcine Animal Model

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Michael J. Raife, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc (10) Associate Investigators
James B. Thrasher, CPT, MC
Daniel W. Horne, LTC, MC
Clyde R. Roy, CPT, MC
Deogracia Quinones, MAJ, MC
Craig Donatucci, MAJ, MC

(11) Key Words:
renal trauma
renovascular surgery
bladder augmentation and
substitution

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To provide an opportunity for urologists in training to develop expertise in the surgical techniques which are useful in the management of urinary tract trauma, to include renovascular surgery, renal autotransplantation, and use of various types of bowel segments for augmentation or substitution.

(16) Technical Approach: Animals are subjected, under anesthesia, to simulated urinary tract trauma. Various surgical procedures are performed to allow resident training in management of these situations.

(17) Progress: Due to resident personnel problems, the protocol was underutilized in the past year. However, we did perform the first continent diversion of urine in a patient ever done at FAMC, using the techniques of this protocol. We will resume in October, 1988. This is an important teaching protocol for urology.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/201 (3) Status: Ongoing

(4) Title: Vasovasostomy in the Porcine Animal Model

(5) Start Date: 1986

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Michael J. Raife, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc

(10) Associate Investigators
Craig Donatucci, MAJ, MC
Daniel W. Horne, LTC, MC
Clyde R. Roy II, CPT, MC
James B. Thrasher, CPT, MC
Deogracia Quinones, CPT, MC

(11) Key Words:
vasectomy
vasovasostomy
microsurgery

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To develop and maintain microvascular surgical skills
for vasovasostomy.

(16) Technical Approach: The vasa are isolated, severed, and reanastomosed
using the operating microscope.

(17) Progress: Due to shortages in resident personnel, the protocol was
under-utilized in 1987. We are scheduled to resume in October, 1988. This
has been a very helpful teaching protocol in the past.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/208A (3) Status: Terminated

(4) Title: Medical Readiness Support Program

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Stephen M. Fall, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Card Surg

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The United States Air Force Medical Readiness Program requires that all dental officers be trained to participate as first or second assistants in the operating room during a general mobilization. The dental activity at Lowry Air Force Base is not associated with the USAF Hosptial through which this rquirement can be met. The Department of Surgery, Fitzsimons Army Medical Center, has been requested to provide an annual exercise to familiarize the dental officers with the skills necessary to assist in the operating room.

(16) Technical Approach: Training protocol.

(17) Progress: The protocol was rewritten and given a new work unit number so this work unit number is terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/209A (3) Status: Ongoing

(4) Title: Effects of Nonsteroidal Anti-inflammatory Agents on
Tendon Healing

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Michael D. Getter, MAJ, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
tendon healing
non-steroidal anti-inflammatory
agent

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if NSAID's effect heal rate of
strength in rat tendon model.

(16) Technical Approach: Suture tendon laceration followed by haling
with and without NSAID's.

(17) Progress: No progress on this protocol due to changes in principal
investigator.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/200 (3) Status: Ongoing

(4) Title: Military Boxing Related Injuries, Amended Protocol

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Robert W. Enzenauer, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR. Ophthalmology (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this investigation are the following: (a) to retrospectively determine the impact of significant boxing-related injuries on the US Army, (b) to determine the specific risk of ocular injuries sustained during an instructional boxing program, and (c) to evaluate the advisability of continued promotion of boxing in the military community.

(16) Technical Approach:

(17) Progress: Protocol will come up for continuing review April 1989.

Presentations: Boxing and Eye Injuries. Presented: Southern Medical Meeting, November 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/201 (3) Status: Terminated

(4) Title: Lipid Composition of Normal and Abnormal Foot Pads

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: William G. Winter, MD
David B. Hahn LTC, MC
Oscar K. Reiss, Ph.D.

(8) Facility: FAMC
VAMC, Denver, CO
FAMC
UCHSC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
foot pads
lipid analysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose a) to establish the biochemical composition of the human plantar foot pads, b) to investigate their metabolic activities compared to similar (adipose) tissues at other anatomical sites and c) to attempt to correlate the chemical composition and metabolic activities with their functional performance.

(16) Technical Approach: See Protocol.

(17) Progress: VA funding was not approved. Funds not available through FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/202 (3) Status: Ongoing

(4) Title: Improving Cancer Management Through the Tumor Conference

(5) Start Date: (6) Est Compl Date: 1989-1990

(7) Principal Investigator: Jeffrey R. Clark, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc. (10) Associate Investigators
Daniel T. Tell, MAJ, MC
(11) Key Words: Harris W. Hollis, Jr., LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: FAMC Tumor Board will be one of 22 in the state where in a randomized controlled fashion, multifaceted educational intervention (maintaining a randomly selected control group) will be introduced. The hypothesis is: Given emphasis on stimulating case presentations in a concert of patient management decision making, tumor boards can function as key elements in patient care and medical education.

(16) Technical Approach: The first 6 months will be baseline evaluation of tumor boards as they now exist. Then an interventional education package is randomly introduced to half the boards over one year and impact is seen. the other half receive no intervention. A crossover of intervention will occur after one year for one year's time. Then, six months of final analysis and recommendation made to NCI.

(17) Progress: Progress to date-FAMC is control and as such only attendance figures and case presentations are being forwarded to the project office to date. Protocol started one month ago.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/203 (3) Status: Ongoing

(4) Title: Comparison of Thermography and Standard Techniques for
Detection, Diagnosis and Tracing of Disorders Marked by
Altered Patterns of Peripheral Blood Flow

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Joe Ozaki, COL, MC
Richard A. Sherman, MAJ, MS

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:
thermography
pain
orthopedic disorders

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 66
d. Total Number of Subjects Enrolled to Date: 66
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the optimal utilization of thermog-
raphy in clinical evaluation of the vascular status of the affected area
for patients with orthopedic related pain disorders.

(16) Technical Approach: We will make thermographic recordings of groups
of ten subjects having one of the following conditions each time they
come to Orthopedic Clinic from the initial diagnostic appointment
through post-resolution follow-up: Frostbite, Charcot Joints, Carpel
Tunnel Syndrome, Fibrositis, Sympathetic Distrophy and Peripheral
Neuropathy, Pre-amputation preparation, and Prediction of Bed Sore For-
mation. The clinical evaluations will not be related to the ther-
mographic evaluations until the subject has completed participation in
the study.

(17) Progress: Too few subjects have completed participation in each
subgroup to permit definitive analysis of the data. However, it is
clear that thermography is a powerful tool for tracking changes in knee
pain and RSD.

Publications: Sherman RA, Bruno GM: Thermographic correlates of chronic
pain: Analysis of 125 patients incorporating evaluations by a blind
panel. Arch Phy Med & Rehab, V 68, May 1987.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/200 (3) Status: Ongoing

(4) Title: ALCON Surgical Intraocular Lens Study

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Floyd M. Cornell, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:
intraocular lens

Jonathan Stock, MAJ, MC
Norman T. Byers, COL, MC
Eric A. Sieck, CPT, MC
William M. Mauldin, LTC, MC
John Pope, COL, MC
Miles Whitaker, CPT, MC
Robert W. Enzenauer, MAJ, MC
William Walton, CPT, MC
David R. Pernelli, CPT, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 10 _____
d. Total Number of Subjects Enrolled to Date: _____ 14 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: Adjunctive study with FDA for intraocular lenses used
following cataract extraction.

(16) Technical Approach: Intraocular lenses are implanted into the anterior
segment of the eye following cataract extraction either as a primary procedure
or as a secondary procedure.

(17) Progress: All lenses in place are doing well. No adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/201A (3) Status: Ongoing

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Stephen M. Fall, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Cardiothoracic

(10) Associate Investigators
Dick E. Smith, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To conduct training courses in Advanced Trauma Life Support (ATLS).

(16) Technical Approach:

(17) Progress: The protocol is scheduled for continuing review January 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88	(2) Protocol WU#: 88/202	(3) Status: Ongoing
(4) Title: A Comparison of Clinical Features of Ulnar Nerve Compression at the Elbow Before and After Medial Epicondylectomy		
(5) Start Date:	(6) Est Compl Date: 1989	
(7) Principal Investigator: David Bizousky, CPT, MC	(8) Facility: FAMC	
(9) Dept/Svc: SUR/Orthopedics	(10) Associate Investigators James C. Johns, MAJ, MC Effy Brewster, COL, MC Jack Fullerton, MAJ, MC	
(11) Key Words: nasal compression carduction velocity		
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this Report.	(13) Est Accum OMA Cost:*	
(14) a. Date, Latest IRC Review: _____ b. Review Results: _____ c. Number of Subjects Enrolled During Reporting Period: 12 d. Total Number of Subjects Enrolled to Date: 12 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".		
(15) Study Objective: Assess results of medial epicondylectomy in the treatment of cubital tunnel syndrome.		
(16) Technical Approach: Comparison of preoperative and postoperative clinical and electrical parameters.		
(17) Progress: Patients currently enrolled and followed in study until sufficient number reached.		
Publications and Presentations: None		

FAMC A.P.R. (RCS, MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/203 (3) Status: Ongoing

(4) Title: Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective) Utilizing Anterior Rhinometric Techniques

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Michael L. Lepore, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Otolyn/Hd&NkSur. (10) Associate Investigators

(11) Key Words:
rhinomanometry
nasal obstruction
nasal surgery

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (a) to utilize anterior rhinometric principles in the pre-op assessment of patients prior to nasal surgery, (b) to utilize anterior rhinometric principles in the post-op evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery (opened or closed), and (c) to determine, utilizing anterior rhinomanometric techniques, if the unobstructive nasal cavity after nasal surgery (opened or closed) is significantly altered at the expense of correcting the pre-op obstructive side, and is this subjectively noted by the patient to the point of causing secondary obstructive symptoms, of any degree on the unobstructive side which will be objectively measured.

(16) Technical Approach: Measurements of nasal airflow utilizing anterior rhinomanometry will be performed before surgery and after surgery at definite periods. Correlation will be made between the various surgical procedures and the measured test results to note if any significant alterations on the unobstructed side have resulted from the surgical procedures.

(17) Progress: Since receiving the equipment in transfer from Brooke Army Medical Center in July, I have not yet tested the equipment. The room that was to be utilized has since been occupied by a new staff member. We are currently making arrangements to occupy another room in building 505. Project should begin in November after it has been tested by the company and principal investigator.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/204 (3) Status: Completed

(4) Title: Biomechanical Analysis of Tibial Fractures Treated
with Intramedullary Nails

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Alexander Pruitt, MAJ, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
Thomas G. Frierhood, MD

(11) Key Words:
tibia fractures
biomechanics
intramedullary nails

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost: *
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To show whether or not the compression forces
across the tibia fracture may be of benefit in predicting fracture heal-
ing.

(16) Technical Approach: Cadaveric tibias were reamed and nailed with a
standard tibial nail that is routinely used in tibia fractures and this
was biomechanically analyzed with the Instron dynamic loading apparatus.
This was correlated with another study and looking at retrospective
analysis of patients that were treated this way.

(17) Progress: This study has been completed as it is currently written
and an addendum is currently pending to analyze not only reamed
intramedullary nails which has already been done; but unreamed
intramedullary nails and dynamic compression plates were two other al-
ternative methods of fixation of tibia fractures. The equipment is
available here at Fitzsimons through normal channels and amounts to just
repeating the original biomechanical analysis with different types of
fixation. This should be a minimal addendum to the study.

Publications and Presentations: This paper, after its completion, was
presented at the American Academy of Orthopedic Surgeons in Atlanta, GA,
in February 1988, at a Scientific Exhibit, and is currently being
processed as a manuscript for publication in the Journal of Bone and
Joint Surgery.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/205A (3) Status: Ongoing

(4) Title: The Use of Gore-Tex Soft Tissue Patches in Repair of Lid
and Adnexal Defects in New Zealand White Rabbits

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Norman T. Byers, COL, MC

(9) Dept/Svc: SUR. Ophthalmology (10) Associate Investigators
Eric A. Cohn, CPT, MC
(11) Key Words: David R. Pernelli, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the animal species in question,
the New Zealand White rabbit, will demonstrate specific orbital and
anatomical considerations to enable further research in lid reconstruc-
tion with Gore-Tex soft tissue patch (polytetrafluoroethylene-PTFE) for
lid defects secondary to tumor or wartime injuries.

(16) Technical Approach:

(17) Progress: This study is scheduled for continuing review March 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/206 (3) Status: Ongoing

(4) Title: An Analysis of the Effect of Nonsteroidal Anti-Inflammatory Medications on Regeneration of Articular Cartilage in New Zealand White Rabbits Treated by Intermittent Active Motion and Continuous Passive Motion

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Alexander Pruitt, MAJ, MC
Anthony W. Colpini, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

Joe K. Ozaki, COL, MC

Cris Myers, CPT, MC

(11) Key Words:
articular cartilage regeneration
continuous passive motion
nonsteroidal anti-inflammatory

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The object of this protocol is to determine whether non-steroidal anti-inflammatory medications have an effect upon the regeneration of articular cartilage in rabbit knees. We are also attempting to delineate whether two separate nonsteroidal anti-inflammatories have different effects on regenerative of articular cartilage treated with continuous passive motion.

(16) Technical Approach: The rabbit knees will be arthrotomized and pieces of the articular cartilage will be moved and the knees will be closed, and then the rabbits will either be put on continuous passive motion on one leg and active intermittent motion on the other, after both arthrotomies. Then they will be reoperated at 4, 8 & 12 weeks, and one group will get no nonsteroidal, one group will get Piroxicam, and one group will get Acetylsalicylic acid.

(17) Progress: Currently the continuous passive motion machine is being fabricated at the metal shop here on post; we are waiting for completion of this; once this is done then we will immediately start with the habituation of the animals to the apparatus. There has been no operation performed on any of these animals for this study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/207A (3) Status: Ongoing

(4) Title: Biomechanical and Histological Analysis of Achilles
Tendon Healing After Open and Percutaneous Repair
in a Rabbit Model

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Anthony W. Colpini, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR. Orthopedic

(10) Associate Investigators
Alexander Pruitt, MAJ, MC
Joe K. Ozaki, COL, MC
Cris Myers, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to compare the
biomechanical strengths and histologic characteristics of healing
Achilles tendon in rabbits that have been repaired using either an open
or percutaneous technique.

(16) Technical Approach:

(17) Progress: This study is scheduled for continuing review April 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/208 (3) Status: Ongoing

(4) Title: A Retrospective Analysis of the Incidence of
Pseudarthrosis in Posterior Spine Fusion Done
Between 1971 and 1986, at St. Anthony's Hospital
and Denver Children's Hospital

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Alexander Pruitt, MAJ, MC
John A. Odom, MD

(8) Facility: FAMC
Lakewood Clinic, Denver, CO

(9) Dept/Svc: SUR. Orthopedic

(10) Associate Investigators
John L. Brugman, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this study is to evaluate those
patients with pseudarthrosis and compare them with an age, sex, and
diagnosed matched group of controls who also underwent posterior spine
fusion but did not develop pseudarthrosis. We propose to evaluate the
contributions of several factors which may effect the incidence of
pseudarthrosis in these patients.

(16) Technical Approach:

(17) Progress: This study is scheduled for continuing review May 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/209 (3) Status: Ongoing

(4) Title: A Comparison of Percutaneous Repair Versus Open Repair
of Achilles Tendon Ruptures

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
R. Todd Hockenbury, CPT, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators
James C. Johns, MAJ, MC
Rick Wilkerson, MAJ, MC

(11) Key Words:
achilles tendon ruptures
percutaneous repair of achilles
tendon ruptures

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: (a) To compare the clinical results of per-
cutaneous repair to open repair of achilles tendon rupture and to inves-
tigate the complications and long-term outcome of these techniques. (b)
To compare the initial repair strengths of these techniques.

(16) Technical Approach: Patients are now being randomized into 2
separate groups and surgery is being performed. The cadaver study is
completed.

(17) Progress: The cadaver study is completed (biomechanical study).
Ten patients have been included into the prospective study thus far.
The proposed total number of patients to be included is forty. The
biomechanical study portion of this protocol has been completed. The
percutaneous repair was found to be 50% weaker than the open repair.
Also the sural nerve was found to be entrapped in three out of five
specimens undergoing percutaneous repair. The prospective study is on-
going with patients being randomized into percutaneous and open repair
groups. We plan to obtain a total of 20 patients in each group. A
chart review of patients having undergone achilles repair at Fitzsimons
is also partially completed. No patients have been cybex tested as of
yet.

Publications:

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" (Submitted for publication, Journal of Foot and Ankle Surgery).

Presentations:

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: The Western Orthopaedic Society National Meeting. Honolulu, Hawaii, October 1988. Winner of the Vernon P. Thompson Award.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Foot and Ankle Society Section of The National Academy of Orthopedics Meeting. Las Vegas, Nevada, February 1989.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Rocky Mountain Chapter Meeting of the Western Orthopedic Society Barnard Lecture Competition. February 1988, and was selected as one of the five finalist papers.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/210A (3) Status: Ongoing

(4) Title: Delayed Repair of Traumatic Intratemporal Facial Nerve Palsy in the Pig

(5) Start Date: May 1988 (6) Est Compl Date: Feb 1989

(7) Principal Investigator: David M. Barrs, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Otolaryngology (10) Associate Investigators
Kenneth F. Casey, MAJ, MC

(11) Key Words:
traumatic facial palsy
nerve graft
intraoperative monitoring

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a. Determine optimal timing for facial nerve repair following temporal bone trauma; b. measure effect of stretch injury to facial nerve in cerebellopontine angle; c. refine direct facial nerve stimulation technique in the temporal bone; and d. develop an animal model for facial nerve study in the temporal bone.

(16) Technical Approach: The facial nerve is cut in the temporal bone and nerve grafted at intervals from immediately to three months after trauma. Histologic and electrophysiologic examinations will determine differences in return of function for different times of repair.

(17) Progress: Sixteen of the twenty study animals will have had their initial surgery performed by the date of this report, and all survival surgery is scheduled to be completed by November 7, 1988. No untoward complications have occurred. Exposure keratitis which was the major concern after facial paralysis has failed to be a problem. This is a new protocol for FY 88.

Publications and Presentations: None-no data yet available.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/211 (3) Status: Ongoing

(4) Title: Double Blind Crossover Study of Cyclobenzaprine versus Placebo in Patients with Primary Fibrositis: Correlation of Symptomatic versus Thermographic Criteria of Improvement

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Anthony W. Colpini, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedic (10) Associate Investigators: Alexander Pruitt, MAJ, MC
(11) Key Words: Richard A. Sherman, MAJ, MS

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study are to compare Flexeril versus Placebo in the treatment of fibrositis, and to evaluate how subjective improvement of either drug or placebo corresponds to normalization of the thermogram.

(16) Technical Approach:

(17) Progress: This study was approved pending revisions. Revision has not been received as of this date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/212 (3) Status: Ongoing

(4) Title: Prevention of Nosocomial Pneumonia and Gastroduodenal
Ulcer Prevention in Mechanically-Ventilated Patients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
William Marx, DO, MAJ, MC

(9) Dept/Svc: SUR/Intensive Care (10) Associate Investigators
Kevin Dwyer, MD
Brant Thrasher, MD

(11) Key Words:
nosocomial pneumonia
gastroduodenal ulcer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To decrease the incidence of pneumonia
(nosocomial) in mechanically ventilated patients receiving antiulcer
prophylaxis.

(16) Technical Approach: 4 groups of patients will be sequentially as-
signed to high, low, and moderate risk (based on APACHE score) to
receive either Cimetidine and antacids; Cimetidine, antacids,
Tobramycin, Polymixin B, Amphotericin; Famotidine or Sulcralfate; GI
bleeding will be noted; routine cultures will be performed.

(17) Progress: Awaiting funding via Henry B. Jackson Foundation.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 72/302 (3) Status: Ongoing

(4) Title: Comparison of Metabolic and Functional Changes in Defects of Platelet Function

(5) Start Date: 1972

(6) Est Compl Date:

(7) Principal Investigator:
T.P. O'Barr, DAC

(8) Facility: FAMC

(9) Dept. of Clin Investigation

(10) Associate Investigators

(11) Key Words:
platelet function tests

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To correlate biochemical and functional parameters of gain a better understanding of the pathophysiology of the disorders of platelet function.

(16) Technical Approach: Platelet Function Studies: When indicated clinically, platelet counts, bleeding times, platelet adhesion, and whole blood and PRP aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation. Biochemical Studies: Assessment of the content and release of the content of the platelet's subcellular storage organelles (alpha and dense granules) and evaluation of the platelet membrane will include, but not be limited to the following: a) Electron microscopy and mepacrine staining of dense granules; b) Content of platelet factor 4 and B-thromboglobulin activity in the alpha granules; c) Production of platelet-derived growth factor by ³H-thymidine incorporation in 3T3 mouse fibroblasts by platelet lysates; d) Measurement of secreted acid hydrolases (B-glucuronidase, B-galactosidase and membrane P-nitrophenyl phosphatase) activities; e) Membrane glycoprotein and phospholipid content; f) Release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase; g) Mobilization of Ca⁺⁺; h) Other studies as they become available.

(17) Progress: No progress was made this reporting period due to the transfer of the principal investigator. Plan to keep this study ongoing for FY 89, in case a member of the medical staff is interested in this area of research.

Presentations:

- (1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDE): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, CA, February 1973.
- (2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.
- (3) Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infants. Presented: Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.
- (4) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Presented: Vith International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.
- (5) Corby, D.G., and O'Barr, T.P.: Decreased - Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VII Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

Publications:

- (1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). (Abst.) Clin. Res. 21:304, 1973.
- (2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst. p. 107), III Congress, Int. Soc. Thromb. Hemos. (Vienna, Austria), June 1973.
- (3) Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.
- (4) Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration of the Function of Human Platelets. Pro. Soc. Exp. Bio. & Med., 146:96-98, 1974.
- (5) Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.

Publications - continued

- (6) Corby, D.G., and Zuck, T.F.: Newborn Platelet Dysfunction: A Storage Pool and Release Defect. *Throm. & Haemo.*, 36:200-207, 1976.
- (7) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. *Throm. & Haemo.* (Stuttgart), 38:35, 1977 (Abstract).
- (8) Corby, D.G., O'Barr, T.P.: Decrease in α -Adrenergic Binding Sites in Newborn Platelets: Cause of Abnormal Response to Epinephrine? *Blood*, 52:161, 1978.
- (9) Corby, D.G.: Aspirin in Pregnancy: Maternal and Fetal Effects. *Pediatrics*, 62:930, 1978.
- (10) Corby, D.G., O'Barr, T.P.: Decreased Alpha-Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine. *Dev. Pharmacol. & Ther.*, 2:215-225, 1981.
- (11) Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. *Haemostasis*, 10(4):177-232, 1981.
- (12) Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book, "Acquired Bleeding Disorder in Childhood". Masson Publ, p 31-37, 1981.
- (13) Corby, D.G., O'Barr, T.P., and Swanson, E.E.: Evidence for a Deficiency of Alpha-Granule Proteins in the Platelets of Newborn Infants. *Soc. Ped. Res.*, May 1983.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults.
I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977 (6) Est Compl Date: Open-Ended

(7) Principal Investigator: Robert S. Stewart, MAJ, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
John K. Podgore, COL, MC

(11) Key Words:
immunologic diseases

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct 87 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 103
d. Total Number of Subjects Enrolled to Date: 1129
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: Serum gammopathies evaluated by SPEP, IEP, and rate nephelometry. Lymphocyte phenotyping, DNA analysis, and neutrophil activation potential by flow cytometry. Lymphocyte activation determined by quantitative mitogenesis.

(17) Progress: Ongoing.

Presentations:

(1) Brown, G.L., and Heggors, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Acquired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy--Immunology Symposium, Aurora, CO, 21-23 January 1986.

(3) Rickman, W.J., Lima, J.E., and Muehlbauer, S.L.: U.S. Army HTLV-III Testing Program Flow Cytometry Workshop. Presented: 11th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, San Antonio, TX, 18-20 March 1986.

(4) Rickman, W.J.: Epidemiology, Pathogenesis and Military Implications of HTLV-III Infection. Presented: Health Service Command Annual Pharmacy Conference. Aurora, CO, 5-9 May 1986.

(5) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Lymphocyte Subsets in Human Immunodeficiency Virus Infection: A Prospective Study. Presented: 2nd Annual Symposium of the Rocky Mountain Flow Cytometry Users Group, Albuquerque, New Mexico, 10-11 September 1986.

(6) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Human Immunodeficiency Virus (HIV) Natural History Study: Abnormal Proliferation of Leu-7 Positive Suppressor T Cells in Asymptomatic Seropositive Patients. Presented: United States Army AIDS Conference, Arlington, VA, 16-18 September 1986.

Publications:

Smolin, M.R., Hasbargen, J., and Rickman, W.J.: Profound Panhypogammaglobulinemia in a Renal Transplant Recipient. Ann. Int. Med. (in press) 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/302 (3) Status: Ongoing

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Pari L. Morse (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators

(11) Key Words:
microbiology
microbiological techniques

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: FY 88 - Two IFA test kits were evaluated for antibodies to *Toxoplasma gondii*; FIAX Toxo-G for IgG and FIAX Toxo-M for IgM. Both have been extremely useful in the evaluation of AIDS patients. In addition, an ELISA kit for Beta 2- microglobulin is being tested. Preliminary data indicate it could be very useful in evaluating AIDS patients and their stage of disease. It may also be useful in evaluating the effects of AZT on AIDS patients.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985;) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/300 (3) Status: Ongoing

(4) Title: Early Identification of Borrelia burgdorferi Antibody
in Human Sera

(5) Start Date: 1986 (6) Est Compl Date:

(7) Principal Investigator: Sandy L. Tessier, DAC (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
Alan G. Barbour, MD, NIH
Hamilton, MT

(11) Key Words:
borrelia
lyme disease
spirochete

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To develop a sensitive and specific screening assay
to detect human IgM directed against B. burgdorferi. The procedure
proposed here will determine if the avidinbiotin system can detect IgM an-
tibody bound to B. burgdorferi on nitrocellulose paper (NCP).

(16) Technical Approach: Last year our preliminary studies indicated that
the probes currently available against IgG are more sensitive and much more
specific than the anti IgM probes. We are evaluating a new IFA kit using
the FIAX fluorometer system that detects IgG/IgM antibodies to B. burgdor-
feri. The patient sera is being screened by ELISA using anti-human IgG
conjugate and then by the FIAX kit.

(17) Progress: We have received 582 serum samples (paired and unpaired)
from soldiers at Ft. McCoy. 459 (including 12 controls) have been screened
by ELISA and 250 of those have been FIAX-tested. Of the FIAX-tested sera,
94 are paired and in 23 of those soldiers spirochetes were recovered from
the ticks. Eight samples of the 250 were FIAX positive, including 3 paired
sera, indicating the soldiers were pre-exposed. The eight FIAX-positive
samples were also ELISA positive and RPR negative.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/301 (3) Status: Terminated

(4) Title: ELISA and Western Blot Detection of Pneumocystis carinii Antigen in Rat Lung and Human Tissue Culture Models

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:
Richard M. Conran, MAJ, MC
Donald D. Paine, DAC

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators

(11) Key Words:
enzyme-linked immunosorbent assay
pneumocystis carinii

Leo A. Andron, MAJ, MS
Carmen Ramirez, DAC
Sandy Tessier, DAC
Pari Morse, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To identify Pneumocystis carinii (PC) antigens useful for distinguishing clinical from sub-clinical pneumonitis.

(16) Technical Approach: Steroid induced PC pneumonia is produced in rats. Blood and lung tissue are harvested from control and clinically ill animals to study PC specific antibodies and antigens. Antigens are analyzed by gel electrophoresis, transblotting and reaction with specific antibodies. Finding unique antigens in clinically ill animals will indicate the feasibility of applying this diagnostic approach to humans.

(17) Progress: Study terminated due to PCS of principal investigator.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/300 (3) Status: Ongoing

(4) Title: Etiology of Low Back Pain Due to Muscle Tension

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin Invstgn

(10) Associate Investigators

(11) Key Words:
low back pain
environmental recording
surface EMG

Joe E. Ozaki, COL, MC
Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, Ph.D., Denver,
VAMC
Bertram Rothschild, Ph.D.,
Denver, VAMC
John Arena, Ph.D., Augusta, VAMC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 11

d. Total Number of Subjects Enrolled to Date: 11

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the relationship between (a) the intensity and duration of work, (b) patterns of muscle tension, and (c) onset of low back pain. To determine whether patterns of muscle tension occurring during normal daily activities are different among people with (a) chronic low back pain, (b) intermittent pain, and (c) no pain. To determine relationships between patterns of muscle tension observed among relatively young active duty soldiers with intermittent low back pain and relatively older veterans with intermittent and chronic low back pain of muscle tension origin. To determine whether simple preventive measures can decrease intensity and frequency of episodes of pain by changing response patterns of low back muscle tension.

(16) Technical Approach: We will do two week long, continuous muscle tension, activity, and pain recordings of relatively young active duty soldiers with duties ranging from strenuous to sedentary who are either pain free, report intermittent low back pain due to muscle tension, or report almost continuous low back pain due to muscle tension. We will do similar recordings of relatively older veterans having similar activity patterns and similar back pain problems.

If we are able to identify abnormal patterns, we will provide people who clearly show these patterns with behaviorally oriented muscle control treatments or mild muscle relaxants in order to determine the effect of these interventions on muscle contractions patterns and pain.

(17) Progress: Relationships between low back muscle tension, pain, and movement remain consistent as long as subjects are pain free. When they report low back pain, the relationship changes. Consistency decreases as pain intensity and duration increases.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/301 (3) Status: Ongoing

(4) Title: Determination of Mechanisms of Phantom Limb Pain: Phase 2

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators

Joe E. Ozaki, COL, MC

(11) Key Words:
phantom limb pain
mechanisms

Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, MD, Ph.D.,
Denver, VAMC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 24

d. Total Number of Subjects Enrolled to Date: 24

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To use MRI, nerve recording, and other techniques to monitor veteran and active duty amputees who report shocking, shooting, and stabbing descriptors of phantom limb pain while they are experiencing various intensities of pain in order to ascertain the physiological changes which are related to changes in pain intensity.

(16) Technical Approach: We will carry out the pilot for a full proposal in which we would record groups of twenty active duty or veteran amputees four times. In the pilot, only two amputees from each group will participate. Two of the recordings will be at one particular pain intensity while the other two will be at two different intensities. This will permit factoring changes due to time from those due to changes in pain intensity. Each subject will be recorded at about weekly intervals but the exact timing will have to depend on when their pain intensity

changes. The groups will consist of two amputees with (1) only stabbing phantom pain, (2) only shooting phantom pain, (3) only shocking phantom-pain, (4) a combination of all three (which is common), and (5) no phantom pain. The fifth group of amputees without phantom pain is necessary to further evaluate changes which occur in the normal stump over time so we can differentiate them from abnormal changes. We know from our experience in Phase I of this study that twenty is the minimum number of amputees we can have in a group due to normal physiological variability and in variability in reporting pain intensity. However, two per group will give us an idea of whether the following techniques are likely to show any differences at all. We propose to use MRI to record overall stump anatomy, plethysmography to record swelling and internal stump pressure, and signals from the neuroma to record responses to mechanical and other stimuli. Because of its invasive nature, we will carry out only one nerve signal study from the stump. For subjects who report phantom pain, we will perform the test on a day when they report the maximum phantom pain they usually experience. We will compare the results of this recording with those from pain free amputees. Due to its cost, we will do MRI recordings of only one subject per pilot group. Two MRI's will be done for each pilot subject. One will be while the subject is as pain free as they get and the other will be while they are experiencing the most pain they generally expect.

(17) Progress: Only a few subjects have completed participation so results are very initial. However, we have clearly demonstrated that among amputees who experience discrete episodes of cramping phantom pain, spike activity in the surface EMG always begins before report of an episode and the spikes are not present when episodes are not reported. We have also determined that phantom pain changes in intensity with changes in stress, fatigue, and barometric pressure.

Publications:

Sherman R, Bruno G: Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. Orthopedics, 10:1395-1402, 1987.

Sherman R, Sherman C, Bruno G: Psychological factors influencing chronic phantom limb pain: An analysis of the literature. Pain, 28:285-295, 1987.

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 1988, (Abstract).

Presentations:

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Presented at the 19th Annual meeting of the Society for Applied Psychophysiology in Colorado Springs, CO, March 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/302 (3) Status: Terminated

(4) Title: Psychophysiological Etiology and Self-help Treatment of Headache

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
John G. Arena, PhD.

(8) Facility: FAMC
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
Richard A. Sherman, MAJ, MS

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

f. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Protocol terminated.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/303 (3) Status: Ongoing

(4) Title: Mechanism Based Treatments of Phantom Limb Pain

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
Joseph K. Ozaki, COL, MC
Timothy Young, MD, Augusta, VAMC
Robert Rodinelli, MD,
Denver, VAMC

(11) Key Words:
phantom limb pain
treatments

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate the effectiveness of treatments for burning phantom limb pain.

(16) Technical Approach: We will treat four groups of ten amputees each with the same six interventions. The amputees will be grouped by the description of their phantom pain. We will work with those describing their phantom pain as (1) only burning, (2) only cramping, (3) mixed cramping and burning, and (4) shooting / stabbing / shocking. Before treatment begins, there will be a three week baseline in which each amputee will be interviewed and stump muscle tension and heat outflow patterns will be recorded. Each amputee will receive each treatment for one month unless side effects force withdrawal. Treatment months will alternate with three week "washout" periods to permit phantom pain to return to baseline. The treatments will be: (1) topical application of nitroglycerine for mainly venous-side vasodilatative effects, (2) tren-tal to reduce blood viscosity so more blood can reach tissues in the

stump having compromised vascular beds, (3) Nifedipine as a Calcium channel blocker for its known peripheral vasodilatative effects, (4) Cyclobenzaprine for its ability to reduce spasms of local origin without interfering with muscle function, (5) muscle tension recognition and relaxation training for its proven ability to reduce microspasms and tension related to intensification of phantom pain, and (6) body surface temperature recognition and control training for its ability to help people control vasodilation of peripheral vessels while under stress. Subjects will be recorded the same way they were during the baseline at each session to permit objective verification of physiological changes. They will come to the clinic every other week during treatments. At the end of the last treatment, there will be another three week baseline. Following the final baseline, the treatment which proved most effective, if any, will be continued for one year. Subjects will be recorded at monthly intervals. If no treatments are effective, subjects will still be followed for one year but will be recorded at six and twelve months.

17) Progress: Short term results indicate that spasm and muscle tension reduction treatments work well with cramping phantom pain. Insufficient data has been gathered from FAMC subject to report more details.

Publications:

Sherman R, Ernst J, Barja R, Bruno G: Phantom pain: A lesson in the necessity for carrying out careful clinical research in chronic pain problems. Rehabilitation Research and Development, 25(2): vii-x, 1988. (Editorial)

Sherman R, Barja R: Treatment of post-amputation and phantom limb pain. In (K. Foley and R. Payne, eds.) Current therapy of pain. B.C. Decker, Publisher, Ontario, 1988. (Chapter)

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/304 (3) Status: Terminated

(4) Title: Use of Heat Patterns in Evaluation of Spinal Cord
Injured Veterans

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS
Jeffrey L. Ernst, Ph.D.,

(8) Facility: FAMC
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
Janusz Markowski, MD, Augusta,
VAMC

(11) Key Words:
spinal cord injury
thermography
phantom body pain

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To confirm the results of two trials in which sur-
face body heat patterns produced by spinal cord injured (SCI) veterans
were compared with (a) completeness of injury and (b) reported location
of sensations which appear to emanate from areas of the body no longer
connected to the brain through the spinal cord (phantom sensations).

(16) Technical Approach: (a) Differences in trunk heat patterns produced
by complete and incomplete SCI veterans will be evaluated through mul-
tiple recordings of twenty surgically complete SCI veterans and twenty
veterans having similar but incomplete injuries who are matched on all
other clinically important parameters; (b) relationships between heat
patterns and location of phantom sensations will be evaluatd by doing
four thermographic recordings of each of 100 veterans diagnosed as
having complete SCIs and then comparing the patterns with sensations
maps filled out at each session.

(17) Progress: This study was not funded. No subjects were run at FAMC
and the study is now closed. Initial data from the Augusta VA showed
significant differences between complete and incomplete SCI patients.

Publications: Shrman R, et al: Differences between upper trunk heat pat-
terns shown by complete and incomplete spinal cord injured veterans.
Paraolegia, 25: 466-474, 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 88 (2) Protocol WU#: 87/305 (3) Status: Ongoing
-
- (4) Title: Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain
-
- (5) Start Date: 1987 (6) Est Compl Date: 1989
-
- (7) Principal Investigator: Richard A. Sherman, MAJ, MS
John G. Arena, Ph.D. (8) Facility: FAMC
Augusta, VAMC
-
- (9) Dept/Svc: Clin. Invstgn. (10) Associate Investigators
Joe Ozaki, COL, MC
Timothy Young, MD, Augusta, VAMC
-
- (11) Key Words: low back pain
thermography
surface EMG
MMPI
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 51
d. Total Number of Subjects Enrolled to Date: 51
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None
-
- (15) Study Objective: To test the effectiveness of paraspinal surface EMG, the MMPI, videothermography, physical examination, and standard diagnostic procedures for ascertaining objective data concerning the patient's actual low back pain intensity and underlying physical problems.
-
- (16) Technical Approach: We are in the process of performing paraspinal surface EMG and videothermographic recordings of at least 360 subjects with low back pain of six diagnostic categories and who hurt most while in one of six different positions (6 x 6 cell design with ten subjects in a group). Each subject is being recorded four times: Twice while their pain intensity is the same and twice while it varies up or down from the two similar recordings. Thus, each subject is recorded at between two and three pain intensities. This provides data on change with time while pain is constant. All of these subjects are given a modified version of the MMPI designed to differentiate between psychological factors and changes in responses due to presence or absence of low back pain. Each subject is also given a complete orthopedic physical examination and any standard diagnostic procedures not already well documented is done.
-
- (17) Progress: Fifty-one patients have been entered into the study at FAMC to date. There is a consistent relationship between low back muscle tension and low back pain intensity. Thermographic results are inconsistent.

CONTINUATION SHEET FY 88, ANNUAL PROGRESS REPORT Proto. No. 87/305

Publications:

Arena J, Sherman R. Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in different positions. Pain, 1988 (in press).

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/300A (3) Status: Ongoing

(4) Title: Effect of Clonidine on Longitudinal Bone Growth in
Juvenile Sprague-Dawley Rats

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
John K. Podgore, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine if clonidine hydrochloride administration to juvenile rats, over a thirty day period, will increase longitudinal bone growth.

(16) Technical Approach:

(17) Progress: Protocol is scheduled for continuing review January 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/301 (3) Status: Ongoing

(4) Title: Continuous Environmental Recording of Activity, Headache, and Muscle Contraction Level Among Subjects with Tension, Migraine or No Headache

(5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators
John G. Arena, MD, Augusta,
VAMC

(11) Key Words:
headache
muscle tension
environmental recording

John Brugman
Richard Calkins
Crystal Sherman
David Hahn
Jeffrey Ginther

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine relationships between motion, muscle tension in the frontal and trapezius muscles, and onset and intensity of headaches among subjects recorded in their normal environments.

(16) Technical Approach: Subjects wear a small EMG and motion recorder during all working hours for one week. They keep an hourly log of types and activity and pain intensity while wearing the recorder.

(17) Progress: New protocol, no results yet.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary

During the year, eighty-four 91A, B and C personnel were trained in suturing techniques. Ten were from the Department of Pediatrics and 74 from Emergency Medicine Service. Training consisted of an overview of operating room procedure, including aseptic technique and operating room rules of etiquette, instruction in the surgical scrub, proper gowning and gloving technique, and hands-on experience in dry and wet labs. Training was conducted on 21 days, using 29 rats and 15 rabbits. 294 hours of training were provided, requiring 105 hours of training support by Animal Resources Service personnel.

One hundred eleven microsurgery training sessions were conducted, providing 273 hours of training to 16 staff surgeons and residents. Forty-two sessions were conducted for Orthopedic Service, 40 for Plastic Surgery Service, and 30 for Urology Service. One hundred eleven hours of training support were required by Animal Resources Service personnel, and utilized 67 rats and 44 rabbits.

Cardiothoracic Surgery Service utilized three pigs in three sessions in the training with and evaluation of the Bio-medicus pump. Three staff surgeons received 45 hours of training, requiring 36 hours of support by Animal Resources Service personnel.

Three Advanced Trauma Life Support (ATLS) exercises were conducted during the year, using 12 goats in the training of 60 staff physicians in the emergency management of casualties. 240-plus hours of training were received, requiring 150 hours of support by personnel of Animal Resources Service for planning, preparation, pre-op anesthesia induction, surgical preps, anesthesia monitoring, circulating and clean-up.

Seven renal trauma exercises were conducted by Urology Service, using seven pigs in the training of two staff physicians and two residents. Forty-two hours of training were received, requiring 84 hours of support by Animal Resources Service personnel in pre-op anesthesia, surgical preps, circulating and anesthesia monitoring, passing instruments and assisting surgeries, and clean-up.

One kitten intubation exercise was conducted for The American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Ninety physicians and nurses received 90-plus hours of training in resuscitative methods and endotracheal intubation, using 13 kittens and requiring 30-plus hours of support by Animal Resources Service personnel in planning, preparation, anesthesia and clean-up.

Cost of Training

Suture Labs (Rabbits)=	\$115/session x 15 sessions=\$1,725
(Rats)=	105/session x 29 sessions= 3,045
Microsurgery (Rabbits)=	95/session x 44 sessions= 4,180
(Rats)=	85/session x 67 sessions= 5,695
Cardiothoracic Surgery=	175/session x 3 sessions= 525
ATLS Exercises=	175/session x 3 sessions= 525
Renal Trauma Exercises=	175/session x 7 sessions= 1,225
	<u>\$16,920</u>

Under a Memorandum of Agreement, one high school student from the Aurora Public Schools T.H. Pickens Technical Center took on-the-job vocational training as a veterinary aide, receiving 111 hours of training, requiring 166 hours of instruction and supervision by personnel of Animal Resources Service.

DEPARTMENT OF OB/GYN

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/35X-001 Status: Ongoing

(4) Title: Repair of Femoral Artery and Fallopian Tube of Rabbit
and Rat

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Edward G. Lundblad, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Continued training for staff and residents is essential.
Experience will make it possible to evaluate suture material and techniques
for publication.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/351 (3) Status: Ongoing

(4) Title: Section A: Master Protocol for Phase II Drug Studies in the
Treatment of Advanced Recurrent Pelvic Malignancies
GOG 26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Master protocol that is still ongoing for many phase II
agents.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/352 (3) Status: Ongoing

(4) Title: Section C: A Phase II Trial of CIS-Platinum

GOG 26

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients; one partial remission, two with stable dis-
ease. No serious adverse reactions.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/353 (3) Status: Completed

(4) Title: Section D: A Phase II Trial of VP 16

GOG 26

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: VP 16 appears to have minimal activity against ovarian and endometrial adenocarcinoma, squamous cell of the cervix at the dose and schedule tested. This study is completed.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/355 (3) Status: Completed

(4) Title: Section N: A Phase II Trial of DHAD

GOG 26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Minimal activity in ovarian cancer previously treated with doxorubicin. Also minimal activity in previously treated carcinoma of the cervix and non-squamous carcinoma of the cervix. This study is completed.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/356 (3) Status: Completed

(4) Title: Section 0: A Phase II Trial of AZQ

GOG 26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Phillips, COL, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Open only for patients with ovarian carcinoma who are ineligible for the #26-N(DHAD) because of prior doxorubicin exceeding 400mg. This study is completed.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/357 (3) Status: Completed

(4) Title: Section Q: A Phase II Trial of Aminochiadiazone

GOG 26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Phillips, COL, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Minimal activity in previously treated ovarian carcinoma and
squamous cell of the cervix. This study is completed.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/358 (3) Status: Completed

(4) Title: Section R: A Phase II Trial of Progestin

GOG 26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: This study is completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/359 (3) Status: Ongoing

(4) Title: Section S: A Phase II Trial of VM26

GOG 26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Modest activity in previously treated epithelial ovarian carcinoma and squamous cell cervical carcinoma. Four patients; 3 progressive disease, 1 stable, 2 patients living, no adverse effects.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/362 (3) Status: Ongoing

(4) Title: A Clinical-Pathologic Study of Stages I and II Uterine
Sarcomas
GOG 40

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients, surgical-pathological study only, patients
benefit from careful surgical staging, no adverse effects.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/369 (3) Status: Ongoing

(4) Title: The Treatment of Women With Malignant Tumors of The
Ovarian Stroma with Combination VCR, Dactinomycin and
Cytosan (Phase III)
GOG 54

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Treatment with Adriamycin has been deleted. One patient who
is living and free of disease, no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/370 (3) Status: Completed

(4) Title: Hormonal Contraception and Trophoblastic Sequelae After
Hydatidiform Mole (Phase III)
GOG 55

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Completed

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/374 (3) Status: Completed

(4) Title: A Clinical-Pathologic Study of Stages II-B, III and
IV-A, Carcinoma of the Cervix
GOG 63

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Study is completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/376 (3) Status: Ongoing

(4) Title: Ultrastructural Staging and Therapeutic Consideration in
Small Cell Carcinoma of the Cervix (Phase II)
GOG 66

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 0 _____
d. Total Number of Subjects Enrolled to Date: _____ 1 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: One patient; surgical-pathological study only, no treatment
involved, no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/378 (3) Status: Ongoing

(4) Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease

GOG 72

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: One patient, surgical pathological study only, no treatment involved and no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/379 (3) Status: Ongoing

(4) Title: Early Stage I Vulvar Cancer Treated with Ipsilateral
Superficial Inguinal Lymphadenectomy and Modified
Radical Hemivulvectomy (Phase III)
GOG 74

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/380 (3) Status: Ongoing

(4) Title: A Clinical Pathologic Study of Primary Malignant Melanoma
of the Vulva Treated by Modified Radical Hemivulvectomy
GOG 73

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Phillips, COL, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Acquiring acceptable number of patients nationally.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/381 (3) Status: Ongoing

(4) Title: Postoperative Pelvic Radiation in Stages I and II Mixed
Mesodermal Tumors of the Uterus (Phase III)

GOG 75

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/384 (3) Status: Completed

(4) Title: Evaluation of Adjuvant Vinblastine, Bleomycin and Cis-platinum Therapy in Total Resected Choriocarcinoma, Endodermal Sinus Tumor, or Embryonal Carcinoma of the Ovary Pure and Mixed with Other Elements

GOG 78

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Phillips, COL, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words: pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum CMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: This study is completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/351 (3) Status: Ongoing

(4) Title: Danazol in the Treatment of Premenstrual Syndrome

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:

(8) Facility: FAMC

Diane C. Garrow, CPT, MS

(9) Dept of OB-GYN

(10) Associate Investigators
Edward Lundblad, COL, MC

(11) Key Words:

pms
therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if Danazol is effective in treating symptoms of pre-menstrual syndrome.

(16) Technical Approach: A double-blind, cross-over, placebo study in which patients who have documented PMS are treated for 2 months with Danazol and 2 months with placebo. While being treated, patients keep a diary of thier symptoms.

(17) Progress: In FY 87 an improvement in PMS patients was shown when patients were treated with Danazol. We are now looking at subgraphs of symptoms for improvement with Danazol therapy.

Publications and Presentations: Obstetrics and Gynecology, July 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 84/352 (3) Status: Ongoing

(4) Title: Characterization of Steroid Hormones Produced by Short-term Incubation of Luteal Cells Obtained from Macaca fascicularis with Induced Luteal Phase Defects

(5) Start Date: 1985

(6) Est Compl Date: Unknown

(7) Principal Investigator:
Edward Miller, CPT, MC
Charles F. Ferris, CPT, MS

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators
Donald G. Corby, COL, MC
Albert H. McCullen, MAJ, VC
Edward Lundblad, LTC, MC

(11) Key Words:
corpus luteum
intern

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to determine if differences exist between control and luteal phase defect induced cycles in the short-term production of steroids significant during the mid-luteal phase of the menstrual cycle of monkeys. If differences exists, possible new therapy for specific types of infertility may be recommended.

(16) Technical Approach: Luteal cells are obtained 5-8 days post- ovulation by luteectomy. The luteectomy obtained cells are processed, then cultured for 3 hours. The supernatant will be assayed for pregnenolone, progesterone, 17OH progesterone and testosterone using RIA procedures. The differences in assay levels of the steroid production from the control and treated cells will be statistically measured using multiple mean tests.

(17) Progress: Culture and production of luteal cells from the control cycle has been completed. Problems having occurred during the treatment phase have been evaluated. The plan is to rectify past problems but the research has been placed in abeyance by LACUC constraints.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/352 (3) Status: Completed

(4) Title: A Phase II Trial of Methotrexate in Patients with Advanced
or Recurrent Endometrial Carcinoma
GOG 86D

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/353 (3) Status: Ongoing

(4) Title: Evaluation of Cisplatin, Etoposide, and Bleomycin
Induction Followed by Vincristine, Dactinomycin and
Cyclophosphamide Consolidation in Advanced Ovarian
Germ Cell Tumors

GOG 90

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/354 (3) Status: Ongoing
(4) Title: Randomized Clinical Trial for the Treatment of Women with
Selected Stage IAI & IAII & IBII Ovarian Cancer (Phase III)
GOG 95

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators
Torrence Wilson, COL, MC

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/355 (3) Status: Completed

(4) Title: Evaluation of a Shortened Course of Vincristine, Dactinomycin and Cyclophosphamide as Adjuvant Therapy for Immature Teratoma of the Ovary, Stage I, Grade 2, Completely Resected

GOG 84

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/356 (3) Status: Ongoing

(4) Title: A Phase III Randomized Study of Cyclophosphamide and
Cisplatin in Patients with Suboptimal Stage III and
State IV Epithelial Ovarian Carcinoma Comparing Intensive
and Non-Intensive Schedules

GOG 97

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One dead of disease, one partial response, one alive with
no evidence of disease.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/357 (3) Status: Ongoing

(4) Title: Echinoycin in Advanced Pelvic Malignancies

GOG 26W

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George L. Phillips, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient, still receiving therapy, no adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/358 (3) Status: Ongoing

(4) Title: Evaluation of Intraperitoneal Chromic Phosphate After
Negative Second-Look Laparotomy in Ovarian Carcinoma

GOG 93

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.
Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/359 (3) Status: Ongoing

(4) Title: Adjunctive Radiation Therapy in Intermediate Risk
Endometrial Carcinoma

GOG 99

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/350 (3) Status: Ongoing

(4) Title: Radiation Therapy vs No Further Therapy in Selected
Patients with Stage IB Invasive Carcinoma of the
Cervix

GOG 92

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/351 (3) Status: Ongoing

(4) Title: A Phase II Study of the Treatment of Stage III and IV
Disease of Advanced Endometrial Carcinoma and All Stages
of Papillary Serious Carcinoma and Clear Cell Carcinoma
of the Endometrium with Total Abdominal Radiation Therapy
GOG 94

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/352 (3) Status: Ongoing

(4) Title: A Phase II Trial of N-Methylformamide in Patients
with Advanced Pelvic Malignancies
GOG 26V

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/353 (3) Status: Ongoing

(4) Title: A Phase II Trial of Vinblastine (NSC#049842) in Patients
with Advanced Pelvic Malignancies
GOG 26Y

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/354 (3) Status: Completed

(4) Title: A Phase II Trial of Cisplatin and 5-FU in Patients
with Advanced Cancer of the Cervix
GOG 76G

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed, one patient still receiving therapy, no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/355 (3) Status: Ongoing

(4) Title: Intraperitoneal (SWOG8501) Intraperitoneal Cis-Platinum
and Cyclophosphamide IV vs Intravenous Cis-Platinum
and Cyclophosphamide IV in Patients with Optimal
Stage III Ovarian Cancer

GOG 104

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/356 (3) Status: Ongoing

(4) Title: A Phase II Trial of Mitomycin-C (NSC #26980) in Patients
with Advanced Squamous Cell Carcinoma of the Cervix
GOG 76J

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/357 (3) Status: Ongoing

(4) Title: Phase Two Study of the Intraperitoneal Administration
of Cisplatin (NSC#119875) and 5-Fluorouracil
(NSC#19893) in Residual Ovarian Carcinoma
GOG 102B

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOC group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/359 (3) Status: Ongoing

(4) Title: GOG Protocol I02A - Master Protocol for Intraperitoneal
Drug Studies in Residual Ovarian Malignancies after
Second-Look Surgery

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators
Francis J. Major, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Newly approved study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/361 (3) Status: Completed

(4) Title: GOG Protocol 26Z - A Phase II Trial of Leuprolide
Acetate in Advanced Ovarian Carcinoma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators
Francis J. Major, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Due to rapid patient accrual this study has been com-
pleted.

Publications and Presentations: None

DEPARTMENT OF PEDIATRICS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 78/40X-001 (3) Status: Ongoing

(4) Title: Use of Laboratory Animals (Cats) to Teach Medical Skills

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
C. Gilbert Frank, LTC, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Laboratory exercise in FY 88 was successful in teaching intubation/chest tube placement skills to Pediatric House officer. This remains an excellent model for teaching skills.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/403 (3) Status: Ongoing

(4) Title: Rare Tumor Protocol for Childhood Solid Tumor
Malignancies, Ancillary
POG 7799

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators
Thomas Carter, COL, MC
(11) Key Words: Jeffrey Clark, COL, MC
POG protocol Randal Henderson, MAJ, MC
neoplasms Vishnu Reddy, LTC, MC
Michael Edwards, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Two patients have been registered at FAMC, one pt with su-
perficial melanoma of the eye is continuing to do well, in complete remis-
sion. The other patient, a newborn with metastatic undifferentiated sarcoma
of the face has died. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/407 (3) Status: Terminated

(4) Title: National Wilms' Tumor Study-3 Phase III

POG 8000

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study is closed for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/414 (3) Status: Ongoing

(4) Title: NWTs Long Term Follow-Up Study: A Non-therapeutic Study

POG 8158

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons, the study remains open to new patient registrations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 82/420 (3) Status: Ongoing

(4) Title: Intergroup Rhabdomyosarcoma Study III

POG 8451

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Three patients have been entered at FAMC. Two in the current reporting period. The first patient has relapsed with metastatic disease after having completed the prescribed two years of chemotherapy. The patient is still alive. One new patient, who was entered in the past year, achieved a complete remission status of his undifferentiated sarcoma of the pelvis region, but has subsequently died of overwhelming sepsis as a result of severe myelosuppression of the chemotherapy. The other patient who was entered this year with nasopharyngeal rhabdomyosarcoma is currently in complete remission status; however, the patient's parents are refusing further chemotherapy because of toxicity of the drugs. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/401 (3) Status: Ongoing

(4) Title: Prevalence of Endometriosis Externa in Adolescent
Women Complaining of Severe Dysmenorrhea

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:
David W. Wells, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
endometriosis
dysmenorrhea

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: 622

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e". None

(15) Study Objective: An epidemiologic survey of young women will document
the prevalence of symptomatic endometriosis externa in a middle class
primary care population of adolescent women complaining of dysmenorrhea.
This prevalent figure will tell the health care provider how alert he has
to be to this condition.

(16) Technical Approach: This retrospective stage of epidemiologic survey
is designed to isolate by questionnaire those young women who might have
endometriosis and subject them to laparoscopy.

(17) Progress: No work has been accomplished since FY 85, COL Wells will
be the new principal investigator. He will revise the protocol and update
the consent form.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/402 (3) Status: Ongoing

(4) Title: B₂ Microglobulin as a Measure of Renal Tubular Function
in the Neonate

(5) Start Date: 1983

(6) Est Compl Date: 1988

(7) Principal Investigator:
Beverly Anderson, MAJ, MC

(8) Facility: FAMC
St. Louis Children's Hospital
Ronald Portman, MD, U. Texas at
Houston
Gerald B. Merenstein, MD, Univ. of
Colo. Health Sciences Center

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
kidney tubules
natriuretic peptides

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 38 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The purpose of the study is to examine renal handling
of low molecular weight proteins in the neonate at various gestational and
postpartum ages who manifest evidence of normal or abnormal intrauterine
environments as well as extrauterine insults. Recent data has shown that
these insults can cause previously undiagnosed renal damage.

(16) Technical Approach: We will study the effects of these insults on
the neonatal kidney from the standpoint of GFR as well as tubular function.
These will both be evaluated in light of the rapid and profound changes in
fluid and electrolytes in the first days of life. The protocol continues
to be low risk as blood sampling is minimal. The protocol will clearly
benefit the patient as renal damage from the aforementioned insults cannot
be diagnosed in any other fashion with current technology.

(17) Progress: The laboratory evaluations continue to follow the expected
trends, i.e., a change in the Atrial Natriuretic Factor value in newborn
infants between days 1 and 3 of life, and the level of B₂ microglobulin ex-
pected during this period of time. No new information has come to light
since the last approval. No adverse reactions have been reported since the
last protocol approval.

CONTINUATION SHEET, FY 88 ANNUAL PROGRESS REPORT Proto No.: 83/402

Presentations:

- (1) Portman, R.J.: B2 Microglobulin as a Marker of Renal Tubular Injury in the Neonate. Presented: COMPRA, Aspen, CO 1984.
- (2) Portman, R.J., Cole, J.: B2 Microglobulin as a Marker of Renal Tubular Injury in the Full Term Neonate with Meconium Stained Amniotic Fluid. Presented: National Student Forum for Research by Medical Students, New Orleans, LA, 1983. Winner of the best renal paper.
- (3) Portman, R.J.: B2 Microglobulin as a Measure of Tubular Damage From Meconium Staining of the Amniotic Fluid. Presented: The USPS 1984 - Finalist for the Ogden Bruton Award.
- (4) Portman, R.J.: B2 Microglobulin as a Marker of Renal Tubular Dysfunction. Presented: Society for Pediatric Research, San Francisco, CA, 1984.
- (5) Portman, R.J., Anderson, B.: Atriopeptin as the Cause of the Diuresis in the Newborn in the First days of Life. Presented: COMPRA, Aspen, CO 1986.

Publications:

Cole, JW, Portman, RJ, Perlman, J, et al: Urinary B2 Microglobulin in Full Term Newborns: Evidence for Proximal Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid. Pediatrics, 76:958-964, 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/401 (3) Status: Terminated

(4) Title: Evaluation of Adrenocorticotrophic Hormone (ACTH) in the Prevention of Cancer Chemotherapy Induced Nausea and Vomiting in Children

(5) Start Date: 1985

(6) Est Compl Date:

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

Michael Shull, CPT, MC

(11) Key Words:

Kenneth Beougher, MAJ, MS

drug therapy

Michael Edwards, CPT, MS

adrenal cortex hormones

corticotropin

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: 4

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Evaluate the effectiveness of ACTH in decreasing nausea and vomiting in children undergoing cancer chemotherapy. To evaluate the toxicity of ACTH and thorazine in this setting.

(16) Technical Approach: This will be a multi-center, double blinded, randomized, crossover study with patients serving as their own control. Patients undergoing at least two courses of identical cancer chemotherapy will be randomized at the beginning of the study to receive either of 2 combinations of antiemetics; (a) ACTH with thorazine or (b) placebo with thorazine. Patients will then receive the other combination prior to their next course of chemotherapy. Extent of nausea, vomiting, side effects and patient preference will be measured and compared between the 2 combinations of antiemetics.

(17) Progress: In FY 87 no new patients have been entered on study. Currently, there have been four patients entered on study, one at FAMC, three at Brooke Army Medical Center. Toxicity has been mild and related to side effects of the thorazine, such as drowsiness and dry mouth. There have been no other toxicities noted. Both treatment arms have been well tolerated. A major problem with this study is the difficulty of recruiting eligible patients to receive the treatment arm with ACTH. Also, our further difficulty is that the ACTH is given IM which necessitates three IM

injections. Because of this the study has been discussed with other coordinators at the other institutions with the possibility of modifying the protocol to include IV ACTH. No formal replies have been received. At this point, I request that the protocol be terminated.

Presentations:

Mosijczuk, A.D.: Evaluation of Adrenocorticotrophic Hormone (ACTH in the Prevention of Cancer Chemotherapy Induced Nausea and Vomiting in Children. Presented: Uniformed Services Oncology Consortium Meeting, Orlando, Florida, April 1986.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 85/406 (3) Status: Completed

(4) Title: Live Attenuated Oka/Merck Chickenpox Vaccine in Healthy Children in Day Care Centers

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: John K. Podgore, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words: varicella vaccine Myron J. Levin, M.D.
U Co. HSC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: In order to determine if the live varicella vaccine administered during the study induces sustained immunity comparable to naturally acquired varicella infection. Follow-up blood specimens for antibody determination are requested at approximately 12-16 months and 24-28 months post vaccination.

(16) Technical Approach: See Protocol

(17) Progress: Follow-up was done on 18 subjects. Determination of immunity is pending lab analysis. Full report and results will be submitted when data is analyzed.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/401 (3) Status: Terminated

(4) Title: Initial Induction Failures in Childhood Acute
Lymphoblastic Leukemia, A Group-Wide Pilot Study
POG 8461

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC. The study is closed
to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/403 (3) Status: Ongoing

(4) Title: Prophylactic Intravenous Immunoglobulin for Infections
in High Risk Neonates

(5) Start Date: March 86 (6) Est Compl Date: 1989

(7) Principal Investigator: C. Gilbert Frank, LTC, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators
Beverly A. Anderson, MAJ, MC

(11) Key Words:
high risk neonates
prophylactic IVIG

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To evaluate in a double blind manner the effective-
ness compared to an albumin placebo of IVIG preventing infectious disease
and/or reducing morbidity and mortality in the high risk neonate.

(16) Technical Approach: 2,000g, 34 wks gestation are eligible for the
study. Routine evaluations and therapy will be given as necessary to all
infants. IgG antibody titers will be drawn pre and post infusion as well
as at 1,2, and 8 weeks. The incidence of infection as well as mortality
and morbidity will be evaluated.

(17) Progress: Study is ongoing with entry of patients into study not only
at Fitzsimons but in other participating institutions. This is a double-
blind placebo controlled multicenter study administered out of Walter Reed.
Results not yet available. There continues to be scattered reports of ef-
ficacy of human immunoglobulin in prevention of neonatal infection. No ad-
verse reactions or withdrawals.

Publications and Presentations: Prophylactic Intravenous Immunoglobulin
(IVIG) in High Risk Neonates. Presented. 16th Aspen Conferece on Perina-
tal Research (ACPR) Aspen, CO July, 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/404 (3) Status: Terminated

(4) Title: Intensive Chemotherapy (MOPP-ABVD) plus Low-Dose Total
Nodal Radiation Therapy in the Treatment of Stages IIB,
III₂A, IIIB, IV Hodgkins Disease in Pediatric Patients,
A Groupwise Pilot Study
POG 8426

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC. The study is closed
for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/406 (3) Status: Ongoing

(4) Title: Infant Leukemia Protocol, A Group-Wide Pilot Study
POG 8493

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One pt. was treated according to this protocol at FAMC after transferring from Brooke Army Medical Center. The child did well until approximately nine months after diagnosis when she developed progressive leukemia and subsequently died 10 months from diagnosis. Toxicity was mild to moderate myelosuppression with no other unusual toxicities. No new patients have been entered in the past year. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/407 (3) Status: Terminated

(4) Title: Treatment of Children with Newly Diagnosed Acute Non-Lymphoblastic Leukemia Using High-Dose Cytosine Arabinoside and Etoposide + Azacytidine for Intensification of Early Therapy, POG Pilot Study

POG 8498

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at FAMC. The study is closed to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/408 (3) Status: Ongoing

(4) Title: Laboratory Classification in Acute Lymphoid Leukemia of
Childhood (ALinC 14C) Phase III
POG 8600

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: During the past fiscal year, four new patients (CB, CO'N,
MP, RE) have been entered on study. Three additional patients at FAMC are
on this study, having been entered more than one year ago. One of those
patients was entered at Walter Reed and transferred here. Since this is a
laboratory classification study, there is no toxicity. The study is ongoing
and is open to new pt. entry. One of the patients (MP) entered on
study during this past year has a unique ALL phenotype. The patient has
markers on T-cell ALL as well as being Philadelphia chromosome positive.
This is a new finding in the protocol and in the Pediatric Oncology Group.
The study is ongoing and is open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/409 (3) Status: Ongoing

(4) Title: ALinC #14 Pharmacology: A Pediatric Oncology Group
Non-Therapeutic Study
POG 8601

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: The study is ongoing and is open to new patient entry. Six
patients at FAMC are currently on this study. Four having been entered in
the past fiscal year. This is a pharmacology study designed to measure
Methotrexate and red cell folic acid metabolite levels. All six patients
remain on study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/410 (3) Status: Ongoing

(4) Title: ALinC #14: Evaluation of Treatment Regimens in Acute
Lymphoid Leukemia of Childhood (ALinC#14) - A Pediatric
Oncology Group Phase III Study
POG 8602

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: There are currently five patients on this study. Three of
whom (CB, CO'N, and RE) who were entered in the past fiscal year. One of
the five patients on study were entered at Walter Reed and transferred to
FAMC. This patient has subsequently transferred to Roswell Park Memorial
Institute in Buffalo, New York. A previous patient diagnosed at FAMC has
subsequently been transferred to Travis Air Force Base and continues on
protocol with information being related periodically to principal inves-
tigator at Fitzsimons. Significant toxicity in two of the five patients
has included severe myelosuppression, septicemia in one patient, secondary
to high-dose Methotrexate and high-dose Ara-C chemotherapy as per protocol.
Otherwise, patients are tolerating therapy well and all remain in complete
remission status on treatment. The study remains open for new patient
entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/411 (3) Status: Terminated

(4) Title: Diagnosis and Therapy of Glomerular Hyperfiltration in
Pediatric Patients with Type I Diabetes Mellitus

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: (8) Facility: FAMC
Robert H. Slover, LTC, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Ronald J. Portman, MAJ, MC
(11) Key Words: Kerry R. Johnson, CPT, MC
Charlotte Stahl, RD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: Principal Investigator did not fill in.

(16) Technical Approach: Principal Investigator did not fill in.

(17) Progress: We enrolled 20 patients, and were unable to gain statistically significant data. We found the study impossible to perform with adequate precision without a CRC and committed personnel. Patient compliance was low and dropout rate was high. It has become apparent that we will be unable to bring enough patients accurately through the entire study to provide meaningful information.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/412 (3) Status: Terminated

(4) Title: Adolescent Oral Contraceptive Study: A Comparison of a Triphasic Formulation (Triphasil) with a Fixed-Combination Pill (Ortho-Novum 1/35)

(5) Start Date: 1986

(6) Est Compl Date: 1988

(7) Principal Investigator:
Charles S. Horn, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Adol. Med.

(10) Associate Investigators
David W. Wells, COL, MC
CPT Schaffrinna

(11) Key Words:
oral contraceptives
comparison

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 60

d. Total Number of Subjects Enrolled to Date: 60

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Compare the clinical usefulness of a triphasic oral contraceptive with a standard, fixed-combination, low-dose pill in an adolescent patient population.

(16) Technical Approach: Patients that agree to enter the study will be randomized by the pharmacy into one of two groups: a) Triphasil and b) Ortho-novum 1/35. An induction questionnaire and physical will be obtained. Subsequent at 1,3 and 6 month intervals the patients will be contacted and further information obtained. If the patient decides to discontinue pill use a discontinuation form will be filled out.

(17) Progress: Compliance was one of the greatest difficulties encountered. Even so, I was able to partially complete over 30 subjects. The information was sent to Dr. Horn for his evaluation. Unfortunately, the study had to be terminated after an error in the pharmacy was uncovered. Apparently, a substitute during illness gave out pills not in keeping with the randomization protocol. This invalidated a number of subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/400 (3) Status: Terminated

(4) Title: Pilot Protocol for Marrow Relapse on Continuation Therapy
in Childhood Acute Lymphoblastic Leukemia

POG 8594

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study
is closed to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/401 (3) Status: Ongoing

(4) Title: Combined Therapy and Restaging in the Treatment of Stages
I, IIA, and IIIA Hodgkins Disease in Pediatric Patients,
A Pediatric Oncology Group Phase III Study
POG 8625/26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IFC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient was entered at FAMC in the last fiscal year.
The patient achieved complete remission status and is currently doing
well, receiving radiation therapy as per protocol. No toxicities have
been encountered. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/403 (3) Status: Ongoing

(4) Title: Randomized Phase II Study of Carboplatin (CBCDA) vs.
CHIP in Treatment of Children with Progressive or
Recurrent Brain Tumor

POG 8638

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POC group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient, a twelve-year-old girl with recurrent pontine glioma was entered on this study in November of 1986. The patient is currently off chemotherapy, doing well with stable disease. Toxicity has been limited to moderate myelosuppression. The study is open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/404 (3) Status: Ongoing

(4) Title: A Study of Childhood Soft Tissue Sarcomas (STS) Other
than Rhabdomyosarcoma and Its Variants, A Pediatric
Oncology Group Phase III Study
POG 8653/54

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study
remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/405 (3) Status: Ongoing

(4) Title: Front Loading Chemotherapy in Children with Increased
Medulloblastoma
POG 8695

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient was entered at FAMC in April of 1987. The patient suffered severe grade IV myelosuppression secondary to the high-dose Cyclophosphamide as per protocol but recovered. However, during subsequently radiation therapy, the patient developed severe bone marrow hypoplasia lasting for two months but eventually recovered and refused further radiation therapy. He is currently off study, and is alive and is followed at the VA Hospital. The patient achieved at least stable disease status. Nationally, 17 patients have been entered on protocol. Ten patients are evaluable for response. Of these, the following post chemotherapy responses have been documented prior to radiation therapy: CR 2 patients, PR 4 patients, SD (stable disease) 2 patients, progressive disease 2 patients. Most important toxicity has been severe myelosuppression due to the high dose Cyclophosphamide which is expected. Although there have been 2-3 week delays in radiation therapy because of the myelosuppression, most patients have been able to complete chemotherapy and radiation as intended. The study remains open to new patient entry.

Publications and Presentations: Dr. Mosijczuk presented an update on the status of the study at the semi-annual Pediatric Oncology Group Meeting in St. Louis, Missouri in October of 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/406 (3) Status: Ongoing

(4) Title: Effects of Oral Contraceptive Agents on Coagulation
Parameters in the Adolescent Patient

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Patrice T. Gaspard, MAJ, MC
Vishnu Reddy, LTC, MC
Judy Barber, DAC
Patricia Rush, DAC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators

(11) Key Words:
oral contraceptive agents
thromboembolic disorders
clotting factors

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 11
d. Total Number of Subjects Enrolled to Date: 29
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To assess if the newer oral contraceptive agents
used today have effects on the levels of clotting factors in adolescent
patients (specifically Factor VIII, PT, PTT, fibrinogen, Antithromb III,
and protein C).

(16) Technical Approach: Patients have the above studies measured at
baseline, then 3 months, 6 months and one year after being on oral con-
traceptives.

(17) Progress: Twenty-nine subjects enrolled; eleven withdrawals,
specimens on 18 frozen and batched to run by Coagulation Laboratory. No
results yet.
Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/407 (3) Status: Ongoing

(4) Title: Headaches Among Adolescents

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: (8) Facility: FAMC
Michael G. Schaffrinna, CPT, MC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators
Mark Blaedal, COL, MC

(11) Key Words:
headaches
adolescents

(12) Accumulative MEDCASE:*. (13) Est Accum OMA Cost:.*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 923
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine prevalence, type and sex distribution of headaches in adolescents.

(16) Technical Approach: Patients will be given the opportunity to fill out a headache questionnaire when they arrive at the adolescent medicine clinic. Questions were designed to evaluate any headache complaint according to type i.e., migrainous, muscle contraction (tension) or other. The data will then be evaluated to arrive at some demographic information.

(17) Progress: As recommended by the IRC a control trial of the questionnaire was started shortly after approval of the study. After 50 patients enrolled the questionnaire and results were analyzed and questions clarified where necessary or deleted. Current questionnaire began in July and results thus far are good. Of note is the presence of light headedness/dizziness in patients with tension headache. This has to my knowledge not been reported before. I am awaiting higher numbers before this finding will be as significant. FY 87 - finding a large number of patients are not aware that we can aid them with headaches. No adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

- (1) Date: 30 Sep 88 (2) Protocol WU#: 87/408 (3) Status: Ongoing
- (4) Title: Efficacy of Prophylactic Anti-Migraine Therapy in the Adolescent Therapy Patient - A Double Blinded Study
- (5) Start Date: (6) Est Compl Date:
- (7) Principal Investigator: Sharon Freeman, LTC, MC (8) Facility: FAMC
- (9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators
MAJ Miller, MD
LTC Dorsett, MD
Michael G. Schaffrinna, CPT, MC
- (11) Key Words:
migraine headaches
verapamil
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: Determine efficacy of prophylactic verapamil in a double blinded study in adolescent migraine sufferers. At the same time this study would establish a per kilogram dose for younger adolescents.
- (16) Technical Approach: Patients will be evaluated at entry for the diagnosis of migraine headaches with a frequency per history of at least two events per month. Presence of organic disease will be evaluated via physical and laboratory evaluation. If no contraindications to verapamil exist then enrollment will occur. Over the next two months no medications will be given. The patient will see two different neurologists who will again evaluate them and fill out an interval history sheet. If both concur with the diagnosis, the patient will be randomly assigned by the pediatric pharmacy to receive either verapamil or placebo for two months. The patient will be seen every month for evaluation of therapy. At the end of two months, they will have a 7 day washout period. Then they will take the counterpart placebo or verapamil depending on which they were initially assigned. They will again take the drug for two months at which time the study will be completed.
- (17) Progress: After notification of HSC approval, the problem of packaging placebo and active ingredient arose. I was able to locate a manufacturer of opaque capsules. Study is now able to proceed.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/400 (3) Status: Ongoing

(4) Title: T Cell#3 Protocol - A Pediatric Oncology Group Phase Study

POG 8704

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
B. Vishnu Reddy, LTC, MC
(11) Key Words: T cell ALL Randal Henderson, MAJ, MC
John M. Bodlien, CPT, MS

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The one patient entered at FAMC (MP) is an eight-year-old girl who presented with an extremely high white count at diagnosis (852,000) and was found to have T-cell ALL. The patient responded well to initial leukaphoresis and chemotherapy according to protocol. She is currently in complete remission, continuing treatment on study. Toxicity has been the expected severe myelosuppression; however, the patient has had no life threatening toxicities or any episodes of septicemia. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/401 (3) Status: Ongoing

(4) Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma
in Children > 365 Days at Diagnosis

POG 8741/42

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
B. Vishnu Reddy, LTC, MC
(11) Key Words: Randal Henderson, MAJ, MC
treatment of stage D John M. Bodlien, CPT, MS
neuroblastoma Jeffrey R. Clark, COL, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC on this study.
The study remains open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/402 (3) Status: Ongoing

(4) Title: The Effectiveness of Phase II Agents in Untreated
Metastatic Osteosarcoma (MOS) or Unresectable Primary
Osteosarcoma vs Previously Treated Recurrent Osteosarcoma
POG 8759

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
B. Vishnu Reddy, LTC, MC
(11) Key Words: David Hahn, LTC, MC
phase II agents in untreated John M. Bodlien, CPT, MS
or recurrent osteosarcoma Jeffrey R. Clark, COL, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC on this study.
The study remains open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/403 (3) Status: Ongoing

(4) Title: Evaluation of Response and Toxicity of Ifosfamide and
VP-16-213 in Children with Resistant Malignant Tumors

POG 8763

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
John M. Bodlien, CPT, MS

(11) Key Words:
ifosfamide
VP-16

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". ONE PATIENT WAS STARTED ON
TREATMENT ACCORDING TO PROTOCOL ON A COMPASSIONATE BASIS FROM THE NCI.
HE IS NOT OFFICIALLY ENTERED ON PROTOCOL.

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have officially been entered at FAMC on this
study. One patient is being treated according to protocol on a compas-
sionate basis on a one time basis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/404 (3) Status: Ongoing

(4) Title: Ceftriaxone vs Amoxicillin/Clavulanate for Initial
Empirical Therapy of Occult Bacteremia in Children

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Frederic W. Bruhn, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
John K. Podgore, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if one of the antibiotic regimens
used for the empiric therapy of occult bacteremia will be more effective
in preventing serious complications.

(16) Technical Approach:

(17) Progress: Continuing review scheduled November 1988.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/405 (3) Status: Ongoing

(4) Title: Macromolecular Absorption in the Post-Asphyxiated
Small Intestine of the Adult Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Kevin J. Kelly, MAJ, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: This protocol will attempt to demonstrate the
mechanism of movement of whole protein macromolecules through small in-
testinal absorptive cells which have been subjected to an asphyxial in-
jury.

(16) Technical Approach:

(17) Progress: This protocol will not come up for continuing review un-
til January 1989. Principal investigator will submit report next FY.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/406 (3) Status: Ongoing

(4) Title: Efficacy of Methylphenidate in Previously Undiagnosed
Adolescents with Attention Deficit Disorders

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Joan R. Griffith MAJ, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Bradford Miller, MAJ, MC
(11) Key Words: Linda O. Ikle, Ph.D.

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study is to demonstrate the
efficacy of methylphenidate in adolescents with learning problems in
school accompanied by attention deficit disorders but previously un-
dianosed or untreated in childhood.

(16) Technical Approach:

(17) Progress: This protocol will not come up for continuing review un-
til August 1989. Principal investigator will submit report next FY.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/407 (3) Status: Ongoing

(4) Title: Comparison of Growth Response of Growth Hormone
Deficient Children to Two Commercially Available
Preparations of Growth Hormone

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Robert H. Slover, LTC, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: In a randomized double-blind crossover study,
growth response of growth hormone deficient children to two commercially
available growth hormone preparations in equal doses will be compared to
determine if there is any significant difference in growth response be-
tween the two. Growth hormone antibodies will be measured to determine
if there is any significant difference in antigenicity.

(16) Technical Approach:

17) Progress: This protocol will not come up for continuing review un-
til March 1989. Principal investigator will submit report next FY.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/408 (3) Status: Ongoing

(4) Title: The Effect of Human/Animal Interaction on Stress
Levels During Outpatient Pediatric Oncology Visits

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Mary Woolverton, MSW
James J. Elliott, CPT, VC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators
Askold Mosijczuk, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: a. Does the presence and interaction with animals
during outpatient treatment visits have any measurable effect on the
patient's stress level as measured by blood pressure and fingertip
temperature; b. Does the presence and interaction with animals during
outpatient treatment visits have any measurable effect on the patient's
anxiety level (as measured by behavioral questionnaires) or discomfort
(as measured by the visual analog pain scale).

(16) Technical Approach:

17) Progress: This protocol will not come up for continuing review un-
til May 1989. Principal investigator will submit report next FY.

Publications and Presentations:

DENTAL ACTIVITIES

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/550 (3) Status: Terminated

(4) Title: Effect of Salivary Function on Oropharyngeal Bacterial Colonization

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Dan Prucha, COL, DDS
Cheri A. Crane, DDS

(9) Dept/Svc: Dental Activities (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The primary objective is to determine the relationship between oropharyngeal Gram-negative bacterial colonization and salivary dysfunction in medically compromised, elderly, and control patients.

(16) Technical Approach: The data collection instrument consists of four major parts: (1) an interview with medical questionnaire; (2) a brief oral health assessment; (3) a parotid salivary collection; and (4) two bacterial throat cultures. The populations to be evaluated include patients from: VAMC geriatric evaluation unit; outpatients of VAMC geriatric clinic; VAMC NHCU and FAMC healthy outpatients.

(17) Progress: This protocol was under evaluation for funding. Funding was not approved for this study, terminate study.

Publications and Presentations: None

DEPARTMENT OF RADIOLOGY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol
(NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Peter W. Blue, COL, MC

(8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med.

(10) Associate Investigators

(11) Key Words:

adosterone

adrenal glands

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep 87 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: approx. 30

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: No studies were performed this period.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 84/601 (3) Status: Completed

(4) Title: An Evaluation of Computed Tomography of the Chest in
Changing the Stage or Treatment of Patients with
Hodgkin's Disease

(5) Start Date: 1984 (6) Est Compl Date: 1988

(7) Principal Investigator: Kenneth D. Hopper, MAJ, MC (8) Facility: FAMC
WRAMC

(9) Dept of Radiology (10) Associate Investigators

(11) Key Words:
tomography
hodgkin's disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 19
d. Total Number of Subjects Enrolled to date: 107
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To evaluate the routine use of chest CT/C in the ini-
tial staging and evaluation of patients with newly diagnosed Hodgkin's Dis-
ease.

(16) Technical Approach: All patients newly diagnosed with Hodgkin's Dis-
ease both at FAMC and at WRAMC are requested to enter the study. If they
agree, a chest CT will be obtained, even if there is a normal chest x-ray.
The chest x-ray is evaluated using form A by one investigator (ML) without
knowledge of the CT. The chest CT is evaluated by one investigator (KH)
with the use of the chest x-ray. The results are entered on Form B. The
two forms are compared and compared to the patients clinical data on Form
C.

(17) Progress: Completed.

Presentations:

(1) Granger, E., Hopper, K. Diehl, L: An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease (40 cases). Presented: Current Concepts in Internal Medicine, October 1985.

(2) Hopper, K.: An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease (40 cases). Presented: Radiological Society of North America, December 1986.

(3) Giguere J, Diehl L, Hopper K. Granger E, Lesar M: Pattern of Intrathoracic Spread of Hodgkin Disease Assessed with CT. To be presented: Radiological Society of North America, December 1987.

Publications:

(1) Hopper K, Diehl L, Granger E, Barnes M, Lesar M, Baumann J, Ghaed N: Clinical Utility of Thoracic CT in the Initial Staging of Hodgkin Disease. Radiology 1987, 161P:216.

(2) Abstract on presentation #3 above to be published December 1987.

(3) Hopper KD, Diehl L, Lesar M, Barnes M, Granger E, and J Baumann: Hodgkin Disease: Clinical Utility of CT in Initial Staging and Treatment¹. Radiology 1988;169-17-22.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/600 (3) Status: Ongoing

(4) Title: a. The Usefulness of MRI and Transrectal Ultrasound in the Staging of Prostatic Cancer: Comparison to lmm Whole Gland Mounts. b. Artifacts and Variants of the Normal Prostate Seen by MRI and Transrectal Ultrasound: Comparison to lmm Whole Gland Mounts

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Kenneth D. Hopper, MAJ, MC
Daniel Horne, LTC, MC
David Thickman, MD
Gary Miller, MD
Gail Weingast, MD
Michael Manco-Johnson, MD

(8) Facility: FAMC

UCHSC
UCHSC
UCHSC
UCHSC

(9) Dept of Radiology

(10) Associate Investigators
Michael Raife, LTC, MC
Edward Pienkos, LTC, MC
Steve Parker, MAJ, MC
Merlyn Gibson, MAJ, MC
Jerry Sims, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Within the past two years, the usefulness of transrectal ultrasound and MRI in the diagnosis and staging of prostatic cancer has been well demonstrated. There are numerous artifacts and variants within the prostate as seen with these two modalities, however, which are poorly understood. In addition, no study evaluating the efficacy of transrectal ultrasound and MRI in prostate cancer has compared the radiographic findings with histological mounts of the entire gland. We intend to correlate the results of the MRI and transrectal ultrasound to lmm whole gland mounts in order to better understand the aforementioned artifacts/variants as well as tumor extension.

(16) Technical Approach:

(17) Progress: This protocol will not come up for continuing review until March 1989. Principal investigator will submit report next FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/601 (3) Status: Ongoing

(4) Title: Body Fat Determination by Dual Photon Absorptiometry

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Peter W. Blue, COL, MC (8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators
Harry N. Tyler, Jr.

(11) Key Words:
absorptiometry
body fat

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: approx.
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate body fat composition by absorptiometry and other current modalities.

(16) Technical Approach: Each patient will be studied by four methods and the methods compared.

(17) Progress: Study not yet started due to lack of funding.

Publications and Presentations: None

DEPARTMENT OF PRIMARY AND COMMUNITY MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 74/651 (3) Status: Completed

(4) Title: Establishment of and Training in Methods for Special
Studies of Abnormal Hemoglobins and Red Cell Metabolism

(5) Start Date: 1974 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Nicholas C. Bethlenfalvay, MD

(9) Dept of Primary Care (10) Associate Investigators
Joseph Lima, DAC
(11) Key Words: Ian Stewart, DAC
hemoglobin, abnormal Elwyn Chadwick, SSG, USA

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: To establish and conduct training in methods for spe-
cial studies of abnormal hemoglobins.

(16) Technical Approach: To acquaint and to train existing personnel in the
performance of various procedures as they pertain to biochemical study of
hemoglobins and red cell enzymes involved in hemoglobin function.

(17) Progress: There have been no patients referred from the Pediatric and
Adult Hematology services.

Presentations: None

Publications:

(1) Boehme, W.M., Piira, T.A., Kurnick, J.E., and Bethlenfalvay, N.C.: Acquired Hemoglobin H in Refractory Sideroblastic Anemia. A Pre-leukemic Marker. Arch. Int. Med. 138:603-606, April 1978.

(2) Weatherall, D.J., Higgs, D.R., Bunch, C., Old, J.M., Hunt, D.M., Pressley, L., Clegg, J.B., Bethlenfalvay, N.C., Sjolín, S., Koler, R.D., Magenis, E., Francis, J.L., and Bebbington, D.: Hemoglobin H Disease and Mental Retardation, A New Syndrome or a Remarkable Co-incidence?. N. Eng. J. Med., 305:607-612, September 1981.

(3) Bethlenfalvay, N.C., Hadnagy, Cs., and Heimpel, H.: Unclassified Type of Congenital Dyserythropoietic Anaemia (CDA) with Prominent Peripheral Erythroblastosis. Brit. J. Haema. 60:541-550, 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 80/650 (3) Status: Ongoing

(4) Title: Studies of Hemoglobin and Red Cell Metabolism in the
Opossum Didelphis virginiana

(5) Start Date: 1980

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Nicholas C. Bethlenfalvai, MD

(8) Facility: FAMC

(9) Dept of Primary Care

(10) Associate Investigators
J.E. Lima, DAC

(11) Key Words:

opossums
erythrocytes
purine metabolism
glucose metabolism

Elwyn Chadwick, SSG, USA

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: The objective is to investigate/define the energy me-
tabolism in red cells.

(16) Technical Approach: Red cells provided with metabolizable substrates
and radiolabelled purine ribo and deoxyribonucleosides are extracted and
the metabolic trail of the provided material is quantitatively defined by
HPLC/radiochromatography.

(17) Progress: It was found, that unlike in human but similar to rabbit,
Hypoxanthine and formate is readily incorporated into adenine nucleotides
including ATP. As a novel finding, half-millimolar levels of deoxy ATP
were found to be present in opossum RBC, which also contain low adenosine
deaminase activity.

Publications:

- (1) Petty, C., Bethlenfalvay, N.C. and Bageant, T.: Spectrophotometric measurement of Hemoglobin Oxygen Saturation in the Opossum, Didelphis Virginiana. Comp. Biochem. Physiol. 50:273, 1975.
- (2) Bethlenfalvay, N.C., Block, M. and Brown, G.B.: Hemoglobins of the Opossum (Didelphis Virginiana Kerr) I. Developmental Changes from Yolk Sac to Definitive Erythropoiesis. Lab. Animal Sci. 26:106-165, 1976.
- (3) Bethlenfalvay, N.C., Brown, G.L., and Waterman, M.: I. Hemoglobins of the Opossum (Didelphis Marsupialis) II. Electrophoretic and Chromatographic Observations. Lab Animal Sci. 26:908-912, 1976.
- (4) John, M.E., Bethlenfalvay, N.C., and Waterman, M.R.: Oxidation - Reduction Properties of the Hemoglobin of the Opossum Didelphis Virginiana. Comp. Biochem. Physiol. 73B:585-591, 1982.
- (5) Bethlenfalvay, N.C., Waterman, M.R., Lima, J.E. and Waldrup, T.: Cytolic and Membranebound Methemoglobin Reductases in Erythrocytes of the Opossum Didelphis Virginiana. Comp. Biochem. Physiol. 738:594, 1982.
- (6) Bethlenfalvay, N.C., Waterman, M.R., Lima, J.E., Waldrup, T.: Comparative Aspects of Methemoglobin Formation and Reduction in Opossum Didelphis Virginiana and Human Erythrocytes. Comp. Biochem. Physiol. 75A:635-639, 1983.
- (7) Bethlenfalvay, N.C., Lima, J.E., and Waldrup, T.: Studies on the Energy Metabolism of Opossum (Didelphis Virginiana) Erythrocytes. I. Utilization of Carbohydrates and Purine Nucleosides. J. Cellular Physiol. 120:69-74, 1984.
- (8) Bethlenfalvay NC, Lima J, Waldrup, T, and Chadwick, E: Studies of the energy metabolism of opossum Didelphis virginiana erythrocytes. II. Comparative aspects of 2-deoxy-D-glucose catabolism in opossum and human red cells in-vitro. Comp. Biochem. Physiol. 89A:113, 1988.
- (9) Bethlenfalvay NC, Lima, J, Stewart, I, and Chadwick, E: Studies on the energy metabolism of opossum Didelphis virginiana erythrocytes. III. Metabolic depletion with 2-deoxyglucose markedly accelerates methemoglobin reduction in opossum, but not in human erythrocytes. Comp. Biochem. Physiol. 89A:119, 1988.
- (10) Bethlenfalvay NC, Lima JE, Chadwick E: Studies on the energy metabolism of opossum Didelphis virginiana Erythrocytes-IV. Half-Millimolar levels of deoxy adenosine triphosphate in red cells are found associated with low adenosine deaminase activity. (Submitted for publication, Life Sciences, September 1988).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/650 (3) Status: Ongoing

(4) Title: Clonal Fidelity of Erythroid Lineage in
Dyserythropoiesis: An Inquiry Into Ultrastructure

(5) Start Date: July 1987 (6) Est Compl Date: Indefinite

(7) Principal Investigator: N.C. Bethlenfalvay, DAC, MD
V.V. Reddy, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators
C.F. Ferris, CPT, MS
D.B. Mercill, DAC

(11) Key Words:
dyserythropoiesis
ultrastructure
x-ray microanalysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To investigate the aspects of ultrastructural components of erythroid precursors to include elemental composition of these components for determination of their role on erythroid maturation, morphology, the process of erythroid denucleation, and functional differentiation in various dyserythropoietic states.

(16) Technical Approach: Burst forming erythroid colonies will be grown in semi-solid tissue-culture media. Bursts will be isolated, fixed, embedded and evaluated by electron microscopy and concurrent x-ray microanalysis of metallic cellular inclusions.

(17) Progress: Difficulties were experienced in obtaining bursts of sufficient size for study. Funding freeze precluded obtaining material needed for an alternate growth medium. Study will resume after lifting of funding freeze.

Publications and Presentations: None

DEPARTMENT OF NURSING

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 86/700A (3) Status: Ongoing

(4) Title: Introduction to Suturing Techniques Using Outbred Adult Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Sandra W. Johnson, COL, AN
Chief, Dept of Nursing

(9) Dept of Nursing (10) Associate Investigators
LTC Lawrence A. Hamer, AN
SGT Carol West, USA

(11) Key Words:
Suture Techniques Training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 17
d. Total Number of Subjects Enrolled to Date: 84
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To instruct selected Department of Nursing personnel to properly suture traumatic lacerations, to establish and maintain a sterile field during the suturing procedure, to cleanse traumatic lacerations, to instruct the patient to manage the wound and facilitate healing, and to correctly remove suture when healing is complete.

(16) Technical Approach: Following didactic instruction by Ambulatory Nursing Service personnel and demonstration/return demonstration of suturing techniques by Animal Research Laboratory staff, students are detailed to perform at least 1 successful suturing episode under direct supervision of an Emergency Medical Service staff physician to validate learning and clinical competence. Once certified, suturing activities become a part of the staff members' scopes of nursing practice. Skills are revalidated annually to ensure continued competence.

(17) Progress: To date, certified personnel have successfully performed numerous suturing episodes without incident. Therefore, the program appears to be meeting its primary objectives.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/700 (3) Status: Ongoing

(4) Title: A Study of the Clinical Nurse Specialist in the AMEDD

(5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:
A.J. Frelin, COL, AN

(8) Facility: FAMC

(9) Dept/Svc: Nursing

(10) Associate Investigators

(11) Key Words:
role development
role

Nancy Staggers, MAJ, AN
Ass. Prof., School of Nursing
Univ. of California

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this descriptive study is to explore the role of the clinical nurse specialist (CNS) as implemented by the ANC from the perspective of the CNSs now in practice as well as the Nurse Managers where the roles are or could be implemented. (a) to describe the role of the CNS in HSC from the perspective of the practicing CNSs; (b) to describe the role of the CNS in HSC as perceived by ANC officers who rate/senior rate them and by Chiefs of Nursing Departments; (c) to compare the perceptions of these groups regarding role implementation; (d) to describe a normative profile of the ANC officer practicing in the CNS role and (e) to assess potential for the future implementation of this specialty in the ANC.

(16) Technical Approach: Each group will be surveyed using a written mailed survey instrument constructed for this purpose. Data analysis will be directed to describing the role and the normative characteristics of those practicing in the role.

(17) Progress: Surveys have been distributed to practicing CNSs and their raters/senior raters. Collection is estimated to be completed by 30 Sep 88 with analysis to follow.

Publications and Presentations: None

MEDDAC

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 83/902 (3) Status: Ongoing

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: 1982

(6) Est Compl Date:

(7) Principal Investigator:
Martin Artman, MAJ, MC

(8) Facility: FAMC
Ft. Carson Veterinary Activity
and Ft. Carson MEDDAC Emergency
Medical Service
AV 691-7226/7111

(9) Dept of Emerg Med & Vet Svc

(10) Associate Investigators
Michael Sugg, MAJ, MC

(11) Key Words:
emergency medical services

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____ 75
d. Total Number of Subjects Enrolled to Date: _____ 75
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate sheet,
and designated as "(14)e".

(15) Study Objective: This project is a refresher/teaching course in Emergency Medicine operative procedures. It is conducted on a monthly basis for EMS physicians and PA's.

(16) Technical Approach: Under general anesthesia animals are subjected to common emergency medicine operative procedures including venous cutdown, peritoneal lavage, chest tube insertion, and thorocotomy with aortic cross clamp with cardiac laceration repair. At the end of the exercise, the animals are disposed of by lethal injection.

(17) Progress: Held 7 training exercises since September 1987. No animals were available until Feb 1988 due to reductions in animal acquisition. Have had animal lab monthly since Feb 1988 except July 1988. Have enrolled 75 attendees. All attendees report increased procedural skill levels after participation. COL Mark Larsen will replace MAJ Artman as the Principal Investigator. The Associate Investigator will remain the same.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 87/900 (3) Status: Ongoing

(4) Title: Serological Assessment of Lyme Disease Among Soldiers
Training at Fort McCoy, Sparta, Wisconsin

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: Michael W. Hastriter, MAJ, MC (8) Facility: FAMC
Fort Leonard Wood, MO 65473-5700
Preventive Medicine Service
A-581-9471

(9) Dept/Svc: US Army MEDDAC (10) Associate Investigators
Kim Mello, DAC, Fort McCoy,
Sparta, WI
(11) Key Words: lyme disease
ixodes dammini
Paul H. Duray, MD, Yale Univ.
Leo A. Andron, LTC, MS, FAMC
Sandra L. Tessier, DAC, FAMC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 988
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine the number of cases of Lyme Disease
contracted at Fort McCoy among a small population of soldiers at high
risk which are those soldiers bitten by a tick.

(16) Technical Approach: Soldiers training at Fort McCoy who receive
tick bites are initially bled and a second follow-up blood samples is
obtained after 6 weeks. Serum samples will be tested for Lyme Disease
antibodies by the ELISA technique.

(17) Progress: 459 of the total 988 serum samples have been tested by
ELISA and 250 of the 459 have been tested by FIAX. The 250 sera were
comprised of sera from 156 service members (SM) (94 paired and 62 un-
paired samples). Twenty-three of the 94 paired sera were from SM that
had B. burgdorferi positive I. dammini removed at the time the initial
serum samples were obtained. Five of the 23 were positive by FIAX (4/5
positive on both initial and follow-up, 1/5 sero converted with less
than four-fold increase in titer). Western Blot tests ran on all posi-
tive FIAX tests gave banding consistent with known positive controls.
The remaining 529 samples will be screened by ELISA and positives con-
firmed with FIAX and Western Blot. The 529 samples include all Fort
Leonard Wood personnel.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 86 (2) Protocol WU#: 87/901 (3) Status: Terminated

(4) Title: Effect of Patient's Position at the Time of Subarachnoid Puncture on the Incidence of Post-Spinal Puncture Headache

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Alexander S. Rubin, CPT, MC (8) Facility: FAMC Fort Leonard Wood, MO

(9) Dept/Svc: Anesthesia Svc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Protocol was approved pending revisions according to IRC stipulations. No follow-up by Principal Investigator. Administratively terminated.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/900 (3) Status: Ongoing

(4) Title: IOLAB Investigational Plan for the Clinical Study of
Intraocular Lenses

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

Luis E. Colon, MAJ, MC

Fort Leonard Wood, MO 65473-5700

(9) Dept/Svc: Ophthalmology Svc

(10) Associate Investigators

(11) Key Words:

IOL (posterior chamber)

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 8

d. Total Number of Subjects Enrolled to Date: 62

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient.

(16) Technical Approach: Extracapsular cataract extraction with PC IOL secondary intraocular lens (IOL) implants.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/901 (3) Status: Ongoing

(4) Title: Coburn Intraocular Lens Study AT GLWACH

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

Luis E. Colon, MAJ, MC

Fort Leonard Wood, MO 65473-5700

(9) Dept/Svc: Ophthalmology Svc

(10) Associate Investigators

(11) Key Words:

IOL (anterior chamber)

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____

b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 13

d. Total Number of Subjects Enrolled to Date: 13

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient.

(16) Technical Approach: Secondary intraocular lens implant.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None

COMPASSIONATE, EMERGENCY USE PROTOCOLS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: (3) Status:

(4) Title:

Compassionate Use of POG 8495 "A Phase I Study of
Hyperfractionation in Brain Stem Glioma in Children"

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

COL Askold Mosijczuk

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: COL Mosijczuk reported that the patient is responding clinically
and neurologically. This is the third patient enrolled in this study on a com-
passionate basis. COL Mosijczuk has considered presenting the protocol to the
IRC for full review; however, Pediatric Oncology Group is planning to close the
study to new patients.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: (3) Status: Completed

(4) Title: Compassionate Use of "Ciprofoxacin Therapy"
Protocol U87-007

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

LTC James Bales

(9) Dept of Infectious Disease (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Ciprofoxacin therapy for highly resistant pseudomonas
aeruginosa infection under compassionate protocol U87-007 (Miles). Patient is
reported improving.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: (3) Status: Completed

(4) Title:

SWOG 8710

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

MAJ Michael Stone

(9) Dept of Hema/Oncol Svc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Received permission to enroll a bladder cancer patient on a compassionate basis.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: (3) Status:

(4) Title:
Experimental Drug "Ofloxacin"

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

COL Michael E. Perry

(9) Dept of Pulmonary Disease (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Received approval for continuation of compassionate use of experimental drug. COL Perry has provided reports to the IRC regarding continued use of the drug. Sufficient precautions have been taken to protect the subject from adverse effects of the medication.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 38 (2) Protocol WU#: (3) Status:

(4) Title:

Compassionate Use of NCI Protocol I-88-14

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

MAJ David S. Brantley

(9) Dept of Hema/Oncol Svc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Received permission to treat refractory adult acute myelogenous
leukemia patient.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: (3) Status:

(4) Title: **Compassionate Implant (Storz Ophthalmic Inc. Co.)**

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
COL Floyd M. Cornell

(9) Dept of Ophthalmology Svc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Received permission to implant an intraocular lens in a pediatric patient on a compassionate, emergency basis. (Protocol approved at Aug 88 meeting)

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 88 (2) **Protocol WU#:** (3) **Status:**

(4) **Title:**
Compassionate Enrollment in POG 8696/97

(5) **Start Date:** (6) **Est Compl Date:**

(7) **Principal Investigator:** (8) **Facility:** FAMC
COL Askold Mosijczuk

(9) **Dept of** Pediatrics (10) **Associate Investigators**

(11) **Key Words:**

(12) **Accumulative MEDCASE:*** (13) **Est Accum OMA Cost:***
*Refer to Unit Summary Sheet of this Report.

(14) a. **Date, Latest IRC Review:** b. **Review Results:**
c. **Number of Subjects Enrolled During Reporting Period:**
d. **Total Number of Subjects Enrolled to Date:**
e. **Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) **Study Objective:**

(16) **Technical Approach:**

(17) **Progress:** Subject accrual in POG 8696/97 is near completion.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: (3) Status:

(4) Title:

Compassionate IND #124001487 Carboplatin

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

COL George Phillips

(9) Dept of OB/GYN (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: COL Phillips indicated compassionate IND #124001487 Carboplatin was an ongoing compassionate use protocol for a patient originally approved in January 1987.

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